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Peer review AWARE

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Abstract

Peer review AWARE

For products containing volatile organic compounds, like some industrial cleaning agents, a new code has been developed which indicates the risk for exposed users. The method, on which this is based, named the AWARE-method, has limited added value in comparison to the new European legislation on chemicals (REACH). This results from the peer review of the method by the RIVM. The AWARE-method was developed by the University of Amsterdam, by order of the Ministry of Social Affairs and Employment (SZW) to reduce the incidence of organic solvent neurotoxicity.

AWARE wants to stimulate the use of less harmful products by providing insight in the risk of harmful products. The AWARE code allows users to choose the safest product. Producers can determine the relative risk and hazard during product development.

The AWARE method provides an indication of the risk based on a limited method description and justification. Further, the difference in AWARE code between products does not always match with the difference in risks of products. The method could be improved by using the limit values that will be derived for REACH over the coming years. The REACH legislation aims, just like AWARE, at the safe use of chemicals. Also, REACH is a legal obligation and provides additional insights in the safe use of chemicals. AWARE only communicates the relative risk of a product. Therefore, AWARE has limited added value after entry into force of REACH.

Key words:
AWARE, volatile organic compounds, organic solvent neurotoxicity, product safety, workers

Rapport in het kort

Collegiale toetsing van AWARE

Voor producten met vluchtige organische oplosmiddelen, zoals sommige industriële schoonmaakmiddelen, is een nieuwe code ontwikkeld die het risico aangeeft voor gebruikers die hieraan staan blootgesteld. De methode die hieraan ten grondslag ligt, de AWARE-methode, levert ten opzichte van het nieuwe Europese stoffenbeleid (REACH) echter weinig meerwaarde op. Dat blijkt uit een evaluatie van het RIVM van de methode. De AWARE-methode is ontwikkeld door de Universiteit van Amsterdam, in opdracht van het ministerie van Sociale Zaken en Werkgelegenheid (SZW), om het aantal gevallen van de schildersziekte terug te dringen.

AWARE wil het gebruik van minder schadelijke producten stimuleren door het risico van schadelijke producten inzichtelijk te maken. De AWARE-code is bedoeld om gebruikers te laten kiezen voor het veiligste product. Producenten kunnen het relatieve risico en gevaar bepalen tijdens de productontwikkeling.

De AWARE-methode geeft een indicatie van het risico op basis van een onduidelijke beschrijving en beperkte onderbouwing. Bovendien komt het verschil tussen de AWARE-code op producten niet altijd overeen met het verschil tussen de risico's van producten. De methode zou verbeterd kunnen worden door gebruik te maken van de limietwaarden voor risicobeoordelingen die voor REACH worden afgeleid in de komende jaren. De REACH-wetgeving heeft – net als AWARE – als doel een veilig gebruik van chemische stoffen te bereiken. Bovendien is REACH wettelijk verplicht en geeft meer inzicht in veilig gebruik van stoffen. AWARE communiceert alleen het relatieve risico van een product. De toegevoegde waarde ervan is hierdoor beperkt zodra REACH is geïmplementeerd.

Trefwoorden:
AWARE, vluchtige organische oplosmiddelen, organisch psychosyndroom, produktveiligheid, werknemers

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Summary

Organic solvent neurotoxicity through volatile organic compounds is a problem in industries with high uses of these substances in open applications. The risk for this effect and other effects can be reduced by substitution with less hazardous substances. The AWARE (Adequate Warning and Air Requirement) method was developed by the Ministry of Social Affairs and Employment to allow comparison of the hazard potency of products and to stimulate substitution.

A peer review of the AWARE method was regarded necessary before further steps towards the introduction of AWARE were taken. This includes a review of the exposure estimate for $AWARE_1$, the OEL for $AWARE_1$ and the method for the determination of the $AWARE_2$. Further, the compatibility of the AWARE method with the chemical legislations REACH and CLP was determined. Last, a comparison of the AWARE method with other methods with a similar goal was required.

Small teams of experts on the specific parts of AWARE were formed who discussed the specific parts of the AWARE method. Other expert teams discussed how REACH and CLP influences AWARE and made a comparison of AWARE with similar tools.

The $AWARE_1$ exposure model is based on unclear assumptions which can be elucidated more. Also, more research on the uncertainty of the assumptions is necessary. Further, the $AWARE_1$ exposure estimate may not always be a correct estimate to compare the exposure.

The OEL part of the $AWARE_1$ differs from the SER-Leidraad with regard to the actual priority in sources for individual OELs and the derivation of default values. We recommend that OELs as included in AWARE are updated using the criteria from the Leidraad and to use the Kick-off approach for default values. In the near future, DNELs could be used as alternatives for some OELs.

The $AWARE_2$, based on the classification of the preparation, is not very accurate and based on known hazards. The CLP legislation can be used for the $AWARE_2$ but has the same limitations. The DNELs available from REACH will be a much better indication of the hazard potency. Development of an $AWARE_2$ based on DNELs is recommended.

Comparison of AWARE with more or less similar tools shows that there are only a limited number of comparable tools and that AWARE has added value.

REACH has the same goal as AWARE, namely the safe use of substances. Both systems provide hazard and safety information to the user of the final product. The information provided under REACH allows an indirect comparison of the relative hazards of similar products, but as long as the user adheres to the operational conditions and risk management measures the use should be safe.

Overall, it is concluded that AWARE is a useful but imprecise tool to reduce the risks of volatile organic compounds containing products. The precision and the scientific substantiation can be increased based on the recommendations proposed in this report. However, in the long run AWARE has little added value once REACH has been implemented.

1 Introduction

Organic solvent neurotoxicity (OSN) through volatile organic compounds (VOC) is still a problem in industries with high uses of these substances in open applications like cleaning and coating. The risk for this effect can be reduced by several methods including substitution of the VOC with less hazardous substances. Substitution can be realised by direct intervention or by making the risk of the products more transparent. Direct intervention works well in sectors in which only a limited number of VOC are used. However, in sectors with a large range of products containing many different substances, a method which makes the hazards and their potency more transparent can be a more effective tool to encourage substitution. Therefore, the AWARE (Adequate Warning and Air Requirement) method was developed by the Ministry of Social Affairs and Employment (SZW) in co-operation with industry based on existing methods as a simple method to determine and communicate the hazard potency. The AWARE method and its scientific basis is described in the report 'The AWARE code' (Krop et al., 2007). Also, a webtool for the calculation of the AWARE code was developed and made available on the internet (http://213.206.93.221/aware). Further, the use and effectiveness of the method was evaluated in three industrial pilots.

A peer review of the AWARE method was regarded necessary before further steps towards the introduction of AWARE were taken. This includes a review of the exposure estimate for $AWARE_1$, the OEL for $AWARE_1$ and the method for the determination of the $AWARE_2$ and their scientific justifications. Further, it was deemed necessary to determine whether the AWARE method is compatible with the introduction of REACH and CLP. The REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation (EU, 2007) on the risk of chemicals towards human health and the environment contains new requirements to industry such as obligations to provide certain data and to show that the use of the substance is safe. The future CLP (Classification, Labelling and Packaging of substances and mixtures) regulation (CLP, 2007) contains new requirements and criteria for the classification and labelling of substances and mixtures. Last, a comparison of the AWARE method with other methods with the same or a similar goal was required.

This report reviews and comments the AWARE method and its scientific basis, discusses how REACH and CLP influences AWARE and makes a comparison of AWARE with methods with a similar goal.

The AWARE code consists of two digits, namely $AWARE_1$ and $AWARE_2$ separated by a hyphen, for example 800–II. $AWARE_1$ indicates the potency for hazards through the inhalatory routes of all VOC in the product in a single number. The lower the number, the lower the potency. The $AWARE_2$ indicates the potency for all hazards through all routes for all substances in the product in a single Roman numeral of I to V. The lower the number, the lower the hazard. The data required for the determination of the AWARE code is normally available within the public domain.

The $AWARE_1$ is defined as '*the amount of m^3 fresh air, required to ventilate 1 m^3 of the working space, to dilute the evaporated volatiles after applying 1 litre of solvent containing product, at a room temperature of 20°C and an atmospheric pressure of 10^5 Pa, emitted from the surface of the treated object, which may lead to exposure of the worker, without adversely effecting the health of the worker.'*. The $AWARE_1$ is determined from the ratio of the predicted exposure concentration to the Occupational Exposure Limit (OEL) of the VOC. If several VOC are present, the $AWARE_1$ of the product is determined by addition of the $AWARE_1$ for each VOC. The $AWARE_1$ cannot be used as a direct indication of the risk because the risk also depends on other parameters like actual product use,

volume of the room and ventilation. The OEL can be an existing OEL derived at the European or national level. If no OEL is present a default method based on the classification of the substance is provided. A hierarchic priority list for the choice of the OEL is used to avoid disagreement on the selection of the OEL. The exposure level from 1 litre of product applied in 1 m^3 working space is determined from the fraction of the substance in the product and the equilibrium vapour pressure using a static method. This simplification is required to be able to use only publicly available data and a simple method.

The $AWARE_2$ does account for the hazards that are not included in the $AWARE_1$, hazards like irritation, allergenicity, mutagenicity, reproductive toxic effects, and carcinogenicity especially for non-inhalatory exposure. Indication of those hazards is especially important in the case of disperse use of the product (for example spray and brush applications), where not only inhalation, but also dermal exposure may contribute significantly to the total exposure to the product. The $AWARE_2$ is based on the classification of the product (preparation) for human health endpoints according to the Dangerous Products Directive (1999/45/EC). All R-phrases and some other characteristics like pH are connected to an $AWARE_2$ code between II and V based on the severity of the effects, the potency and the presence or absence of a threshold. An $AWARE_2$ code of I is assigned if the product is not classified for human health endpoints. The highest $AWARE_2$ for all R-phrases assigned to the product determines the $AWARE_2$ of the product.

2 Materials and methods

The peer review of the AWARE method was performed on the description of the method and its scientific basis in the report 'The AWARE code' (Krop et al., 2007). Small teams of experts on the specific parts of AWARE from the National Institute for Public Health and the Environment (RIVM) and TNO Quality of Life were formed who discussed the specific parts of the AWARE method. Other expert teams discussed how REACH and CLP influences AWARE and made a comparison of AWARE with similar tools. Opinions were drafted by one member of each team and commented by the other experts until an acceptable opinion was derived. These opinions form the main chapters of this report.

3 Results

This report discusses the AWARE method as described in the report 'The AWARE code' (Krop et al., 2007). It is assumed that the reader has knowledge on the AWARE method and its scientific basis as described in that report.

3.1 $AWARE_1$; Exposure estimation

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3.1.1 Introduction

The emphasis of this section will be on the correctness of the exposure part of the $AWARE_1$-code and the differences with respect to existing product risk coding systems. The aim is to critically review the derivation of the exposure estimation for the $AWARE_1$ code and its argumentation given in the AWARE report. Recommendations are given wherever possible.

3.1.2 A rigorous derivation of the $AWARE_1$

The AWARE is a coding system for products containing VOC. Users/consuments of such VOC-containing products are, inherent to its appliance, exposed to the VOCs by means of their evaporation from the (applied) product. The concentration of the airborne VOC is, besides the toxicity of the VOC, a prerequisite to execute a risk assessment of the exposure to VOC via inhalation. The VOC air concentration is dependent on numerous factors: method of appliance, workspace volume, ventilation, exposure duration, temperature, composition of the products, and many other factors. Consequently, it is infeasible to determine the exposure to VOCs that will cover all potential scenarios. A computer model, after it is validated by means of a standardised exposure experiment, is able to make an estimation of the expected exposure by extrapolating the model to reflect a specific scenario. The $AWARE_1$-code contains a model that represents a standard scenario after applying 1 litre of solvent containing product on a surface at room temperature in a workspace of 1 m^3. The result of the $AWARE_1$ is an estimation of the amount of fresh air necessary to ventilate the 1 m^3 workspace. The $AWARE_1$ is calculated using a mathematical model based on the established Occupational Air Requirement (OAR). Starting point of the $AWARE_1$ code is the Margin of Safety (MoS).
The MoS is defined as the ratio of the Occupational Exposure Limit (OEL) of the VOCs to the predicted exposure concentration, this yields:

$$MoS = \frac{C_{OEL}}{C_{exposure}} \qquad (1)$$

With C_{OEL} the OEL concentration of a particular VOC and $C_{exposure}$ the predicted concentration of this VOC calculated by the $AWARE_1$ evaporation model. In the AWARE approach, the inverses of the MoS of all volatile components are added as if they have similar critical toxicological endpoints. The $AWARE_1$-code claims to be a very conservative estimation of the hazard, since it adds the hazards of all VOC components in the product. This is only true for non-synergistic toxicological endpoints; the possibility of synergy is not considered in the $AWARE_1$ code. Furthermore, the uncertainty in the

calculated exposure concentration is important as it determines the estimated MoS. But on the other hand, the OEL is set conservatively in itself. Nevertheless the magnitude of the uncertainty in the calculated exposure concentration may surpass the conservatism of the OEL. Therefore it is important to perform an uncertainty analysis of the $AWARE_1$ model.
A major assumption on the exposure part of the $AWARE_1$-code is on the activity coefficient γ. The $AWARE_1$-code assumes an activity coefficient equal to 1, which corresponds to Raoult's law. Raoult's law is only appropriate when the molar fraction y^L of the solvent approaches one. Henry found that when $y^L \rightarrow 0$ then $\gamma \rightarrow$ H, with H the Henry coefficient. Both laws approximate the activity coefficient γ for special cases. A more realistic approach would be to consider the activity coefficient as a function of the molar fraction:

$$\gamma = \gamma(y^L) \tag{2}$$

This is especially the case when it is contemplated that the molar fraction y^L of the VOCs would vary throughout evaporation. Besides that, even in the static situation, only **one** of the substances can be present in excess, $y_i^L \rightarrow 1$ than $\gamma_i \rightarrow 1$, whereas the other VOCs $y_j^L \rightarrow 0$ and $\gamma_i \rightarrow$ H. Again this leads us to equation (2). Another (transitional) method to implement equation (2) might be to consider γ equal to one for the main solvent(s) and γ for the solved substances equal to their H (if these are unknown than $\gamma = 1$ as a default). Anyhow it is of the utmost importance that the error made by this assumption is investigated thoroughly (preferably quantitatively). This is lacking in the AWARE-documentation.
A second important assumption made in the derivation of the $AWARE_1$ is that of unchanged product composition during evaporation. This assumption is rather questionable. For example for a VOC that is available in the product in very low quantities. It is possible this VOC never reaches its equilibrium vapour pressure, as its source in the product is exhausted before equilibrium settles. In the theoretical scenario of the $AWARE_1$-model, the volume of the work space (V_{ws}) approaches zero ($\lim V_{ws} \rightarrow 0$) in this case the depletion of the VOC does not play a role, however in a more practical situation this can happen and this is not incorporated in the $AWARE_1$ code.
A third important assumption of the $AWARE_1$ code is the maximum vapour pressure, P^{max} = 30 kPa. This value is set rather arbitrarily as the cut-off point that determines whether VOCs evaporate completely (as the VOCs equilibrium vapour pressure (P_i^{eq}) exceeds 30 kPa) or partially (defined proportionally to the ratio of P_i^{eq} over P^{max}). The choice for the maximum vapour pressure is grounded by the calculation of a typical paint that consists of 50% liquid. Further, assuming a liquid density of 0.8 kg/dm^3 and an average molecular mass of 40 g/mol, a maximum equilibrium pressure of around 30 kPa in the unit working space can be established, according to the authors. If we follow these assumptions we obtain:

$$P^{max} = \frac{n \cdot R \cdot T}{V_{ws}} = \frac{10 \cdot R \cdot 293}{1} = 24 \times 10^3 \text{ Pa} \tag{3}$$

which can be conservatively rounded to 20 kPa (dividing by P^{max}) and not to 30 kPa. In the appendix an alternative derivation of the $AWARE_1$ code is given where the P^{max} is straightforwardly made product-specific. Nonetheless, the influence of the arbitrarily defined P^{max} on the quality of the calculated exposure by the $AWARE_1$ code is uncertain and it may be said that the justification of this assumption is lacking.
In general, the derivation of the $AWARE_1$-code as discussed in the AWARE-document is not very clear. An alternative derivation of the $AWARE_1$-code that is, in our opinion, much more obvious is

given in Appendix 1. Furthermore, it is suggested that the derivation is done in either SI/generic units or explain the conversion factors explicitly (for example the conversion factor 10 (in eq. A.12) results from the conversion of kg to g and the mass percentage to mass fraction, net conversion factor is 1000/100 = 10). Moreover, an alternative derivation of the $AWARE_1$ (and other risk indicators founded on the VOC content of the product in general) in case of exhaustion on the one side and the maximum vapour pressure of that VOC in case of non-exhaustion is presented in equation (A.12).

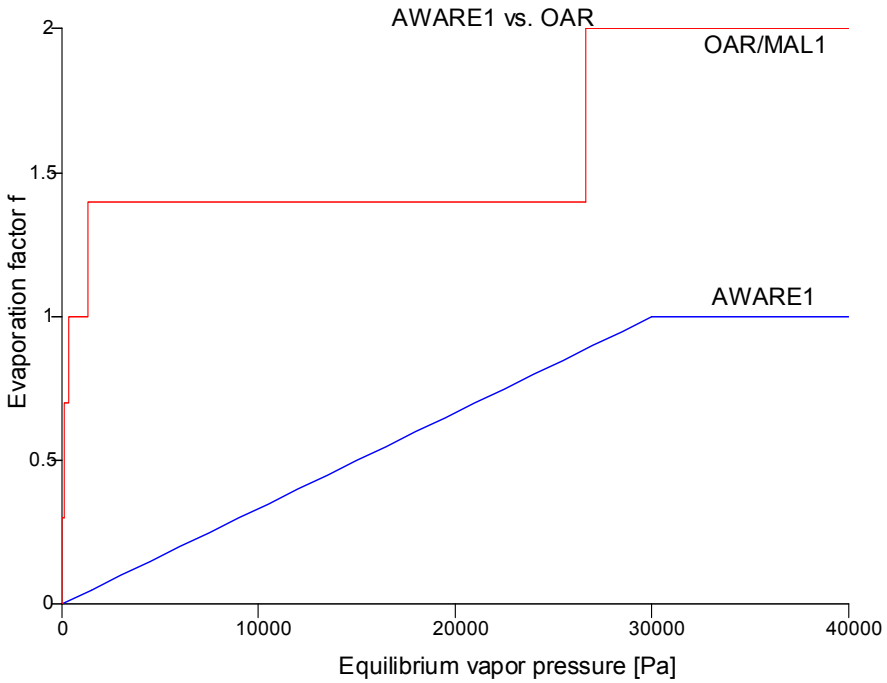

Figure 1. Evaporation factor *f* of the $AWARE_1$-code and OAR/MAL_1-code as function of the equilibrium vapour pressure. The $AWARE_1$'s *f* is for all VOCs lower than the *f* of the OAR/MAL_1

3.1.3 The AWARE and other potential risk indicators

The difference between the $AWARE_1$ and the OAR is minimal. The $AWARE_1$ and the OAR differ from each other solely on the calculation of the evaporation factor (*f*). The quantitative difference between the evaporation factor *f* of the $AWARE_1$ and OAR is shown in Figure 1. The evaporation factor of the $AWARE_1$ is for all VOCs lower than the evaporation factor determined by the OAR method, which makes the OAR more conservative. Although the OAR seems to build on an experimentally determined evaporation factor, the physical-chemical basis for *f* is unclear. Furthermore there is a fundamental problem with the original definition of the evaporation factor as it suggests that for values of *f* exceeding 1 more mass is present in the vapour than originally was available in the product. Therefore we endorse that a new definition of *f* is required.
Other potential risk indicators such as the Required Air Quantity (RAQ), Vapour Hazard Ratio (VHR), Relative Inhalation Risk (RIR), Air Change Index (ACI) (Krop et al., 2007) and the exposure model

developed the Dutch Worker Union (ArboUnie) (Dekker et al., 2007) are all variants of the OAR and its accompanying definition of the evaporation factor *f* and are therefore not discussed in further detail.

3.1.4 Validation of the $AWARE_1$

The fact that there exists no simple relation between the VOC content and the $AWARE_1$ is by no means a validation of the $AWARE_1$ model, it is merely a result and should be discussed in a different chapter. Further it is remarkable to see that the correlation between the $AWARE_1$ and the exposure indexes (Dekker et al., 2007) has a regression coefficient $R^2 = 0.92$ (section 6.3). This seems to be very high, however (a summary of) the data is lacking in the AWARE documentation. Moreover, it is unclear whether this correlation is a model-to-model or a model-to-measurement comparison, therefore it is recommended to show the underlying data. Moreover a high correlation coefficient does not fully reflect a good performance of the $AWARE_1$ model. Other performance criteria, for example the accuracy of the model output and its performance to predict exposure are not addressed. Some indications of the performance of the $AWARE_1$ code can be derived from the decision taken by the ArboUnie to stop the development of their version of the AWARE model, as they observed the AWARE model largely underestimated the measured exposures. In conclusion it can be stated that the level of validation of the $AWARE_1$ model with respect to the estimation of exposure seems to be very limited.

3.1.5 Conclusion

Most often labelling models of VOC containing products lack a clear definition of parameters which could obscure their intercomparison. The OAR, presently the most established screening tool for VOCs, is subject to this problem as well; the physical-chemical basis of the evaporation factor is unclear. On the contrary, the $AWARE_1$ method defines a more obvious and 'physical correct' evaporation factor compared to the OAR. Nevertheless, it is of the utmost importance that the developers of the $AWARE_1$ model elucidate their unclear assumptions. The only method to indicate their assumptions are justified is to perform a quantitative analysis of the uncertainty of the $AWARE_1$ subject to their assumptions. Furthermore, the validation of the $AWARE_1$ code is only done for an experimental setting, application of the $AWARE_1$ in real scenarios is limited (Dekker et al., 2007). We encourage the development of a labelling tool with a correct definition of the evaporation factor but we also conclude that more research on the uncertainty of the assumptions is necessary before the $AWARE_1$ can be implemented.

3.2 $AWARE_1$; OEL

Authors: P.J.C.M. Janssen, M. le Feber, B. Hakkert and C. de Heer.

3.2.1 Introduction

The $AWARE_1$ code is determined by the ratio of the OEL and the predicted exposure concentration. The AWARE report provides a priority list for the selection of the OEL from available OELs and a default method for when no OEL is available. In this chapter the priority list and the default method is compared with the recent guidelines for the determination of OELs as presented by the Social and Economic Council of the Netherlands (SER). Of course different priorities may be required when AWARE is used at a European level.

3.2.2 Comparison of the derivation of the OEL

The choice of OEL as presented in the AWARE-report in general outline follows the recent guidelines ('Leidraad'). These guidelines have been specified in a decision scheme that was recently published (Consortium, 2008). For brevity the guidelines as presented in this decision scheme will be referred to below as the 'Leidraad'. Existing OELs are to be used, the AWARE report indicates, preferably those derived by the European Scientific Committee on Occupational Exposure Limits.

In the electronic AWARE calculation tool the following lists of existing OELs have been included:
- the Dutch OEL-list from 2005;
- for additional substances: OEL-values from the Danish MAL and Norwegian OAR lists;
- for additional substances: OELs as derived by producers.

For mineral spirit fractions the approach as proposed by CEFIC is recommended (described in section 4.6 of the AWARE report). For carcinogens (genotoxic carcinogens) the extra cancer risk level of 10^{-6} /year is recommended for use within AWARE.

In case no OEL is available for a substance the AWARE report proposes the use of a default value based on the hazard classification for the substance. For this, the vapour pressure is divided by a factor of either 30,000, 3000, 1500 or 75 depending on the EU health hazard labelling attached to the substance. For chemicals of low volatility for which no label was necessary the OEL for repirable dust is proposed. This approach is similar to that in de Danish MAL code.

As an alternative, in case an OEL is not available for a particular compound, read-across from chemically related compounds is advocated or a hazard banding based on risk phrases. These approaches have been recommended by ECETOC.

The AWARE report stresses the importance of OEL-values derived by producers, which is in line with the new Dutch framework called 'VAST' developed the Dutch Ministry of Social Affairs and Employment. Another important development, the AWARE-report indicates, is the new European chemicals policy REACH, in which DNELs (derived no-effect levels) are to become available for individual substances, which might then be used as OELs. Like the new VAST programme, REACH allocates a primary responsibility to producers of chemicals in generating toxicity data and their evaluation resulting in appropriate DNELs.

To provide clarity as to the recommended choice of OEL, the AWARE-report presents the following priority order for obtaining an OEL:
1. European OEL (or IOELV = indicative limit value)
2. National OEL (MAC)-value
3. Lowest producers value
4. Lowest value in any other EU-25 or EU-associated country
5. Lowest OEL value in the US-systems
6. Default

This recommendation in general outline follows the approach presented in the SER 'Leidraad' but the actual details of the latter differ. In Table 1 the differences are indicated.

Table 1. Comparison of the priority of OELs between AWARE and the Leidraad

Priority	AWARE	Leidraad
1	EU OEL	Official Dutch limit value ('wettelijke grenswaarde')[a]
2	National OEL (presumably this refers to Dutch values pre 01-01-2007)	OEL as derived by SCOEL (SEG) or DECOS prior to 1997[b]
3	Lowest producer value	Select value from OEL lists from other countries[c] or from safety information sheets supplied by producers[d]
4	Lowest value in any other EU-25 or EU-associated country	
5	Lowest OEL value in the US systems	
6	Default	New derivation of OEL using one of various established methods[e]

[a] This involves a limited set of approximately 100 limit values derived after 1997 either by the Dutch Expert Committee of Occupational Standards (DECOS) or the EU Scientific Committee on Occupational Exposure Limits (SCOEL) and, in addition, some 50 additional limit values for carcinogenic compounds as derived by DECOS. These 150 limit values are in the public domain and are legaly supported by the Dutch Ministry of Social Affairs and Employment. To this number of 150 compounds additional ones may be added in the future based on prioritization by the Ministry.

[b] As an important proviso the Leidraad indicates that the quality control of these values was not well established during this time period and therefore expert advice is needed to validate these values. As an possible alternative, the Leidraad indicates that from 2010 onwards the new chemicals regulation REACH may provide adequate DNELs for worker exposure which should then be used.

[c] This step involves a range of possible quality criteria. Within the Leidraad three categories of lists are distinguished: A. health limit values allocated without consideration of technical and economic feasibility B. Lists of OELs derived with inclusion of feasibility consideration. C. Lists of OELs with unknown method of derivation. In the Leidraad the different lists for various European countries and the USA have been categorised (Examples: US TLVs as derived by ACGIH and German MAK-values are A-lists, OELs from Norway, Sweden, UK are B-lists, OELs from Hungary, Greece, Switzerland, Belgium are C-lists. B- and C-values require validation by an expert, the Leidraad prescribes.

[d] If values can be validated based on an adequate report of their derivation, they can be categorised under either A or B as outlined under the previous footnote. Again here the proviso applies that values classified as B require expert validation. Insufficiently documented producer values require support by an expert, the Leidraad states.

[e] The Leidraad distinguishes three groups of methods: A. Defaults based on R-sentences for substances as published by the European Chemicals Bureau (methods: DOHSBase Kick-off, ECETOC Generic Exposure Values). B. Derivation of a value from appropriate toxicity data according to an established method (REACH, ECETOC, Health Council of the Netherlands) C. Scientifically valid OEL derivation under current standards used by SCOEL, Health Council of the Netherlands or any other competent scientific body for deriving OELs. As to the default the Leidraad indicates a tentative preference for the (German) Kick-off system in which the 10-th percentile of the limit value distribution within hazard categories (based on

R-sentences) is used. It is stressed within the Leidraad that any method used must not not lead to unacceptable underestimation of limit values.

3.2.3 Discussion

The approach for OEL selection as presented within the AWARE report is pragmatic and uses existing values where these are available. In this respect the report agrees well with the SER-Leidraad. However, as to the actual priority in sources for individual values there are substantial differences. OEL-values for individual compounds as present in the AWARE data base of OELs may be expected to often differ from those that would result from following the selection steps as presented in the SER Leidraad. US values for instance are given much lower priority within AWARE. Another difference concerns the default approach based on R-sentences as advocated within the AWARE report. Applying the Kick-off approach would be more in line with Leidraad. Updating the values within AWARE using the selection criteria from the Leidraad would be a useful step. For transparancy individual values could be tagged as to their status and derivation source. In fact this problem of what is the best available OEL for an individual compound, transcends the AWARE method. In the new situation where OELs for a limited number of chemicals only, are available in the public domain, the risk of different values circulating for a particular chemical without clarity about which of these values is best as to the underlying science, will be real. As is also stated repeatedly throughout the Leidraad, expert knowledge is needed in case of uncertainty concerning the validity of OEL values for individual compounds. Also in view of the envisaged use of AWARE on the European level, the option should be considered to have an appropriate expert group apply the general guidance as provided by the Leidraad on a structural basis, thus compiling a comprehensive validated data base in which the best individual OEL-values are presented. Such a data base would not just be useful within AWARE but could also provide more general transparancy as to availability of OELs and to best values in case more than one value has been proposed.

3.2.4 Conclusions

The approach as taken in the AWARE report is similar to that described in the SER-Leidraad. Both are pragmatic approaches using existing OELs. However, as to the actual priority in sources for individual OELs there are substantial differences. Accordingly adherence to the selection criteria from the Leidraad would frequently lead to different OELs compared to the data base of values as incorporated in AWARE. Moreover the latter data base contains all Dutch OELs which have been withdrawn on 01-01-2007 (n=800). Also the default approach as recommended in the AWARE report differs from that recommended in the Leidraad. We recommend that OELs as included in AWARE be updated using the criteria from the Leidraad in order to achieve a data base that provides the user with the best available values from a scientific point of view. Where default values are needed the Kick-off approach should be used (in agreement with the Leidraad). For transparancy and consistency all values should be properly referenced.

3.3 $AWARE_2$

Authors: J.J.A. Muller, M. le Feber, B. Stuurman, C. de Heer and W.C. Mennes.

3.3.1 Introduction

The $AWARE_2$ accounts for the hazards that are not included in the $AWARE_1$, hazards like irritation, allergenicity, mutagenicity, reproductive toxic effects and carcinogenicity especially for non-inhalatory exposure. Indication of those hazards is especially important in the case of disperse use of the product (for example for spray applications), where not only inhalation of vapours, but also dermal exposure and inhalation of aerosols may contribute to the total exposure of the product. The $AWARE_2$ code system is based on the preparation classification system (DPD) (EC, 1999) currently used in the EU. The resulting R-phrases are then assigned an $AWARE_2$ code number (I-V) according to a table based on the 'highest' risk phrase.

3.3.2 Shortcomings

1. The starting point for the derivation of the AWARE is the margin of safety (MoS) according to the introduction of the AWARE report. This is correct for the $AWARE_1$ but not for the $AWARE_2$ because this is based only on hazard. No explanation is provided why the $AWARE_2$ is restricted to hazard. It is assumed that this is because of the practical problems in performing a full risk assessment for a mixture containing several substances for which the toxicology data are only partially known and exposure may occur via several possible scenario's and several routes. We agree with this approach. An explanation of the approach used for the $AWARE_2$ would increase the scientific basis of AWARE.

2. The $AWARE_2$ is based on the assigned R-phrases for the product based on the classification of all components according the DSD (Dangerous Substance Directive) (EEC, 1967) and DPD. However, there is no data requirement in the DSD or DPD meaning that substances without any toxicological data have no R-phrases and thus an $AWARE_2$ of I. Also substances with only limited data will have a low $AWARE_2$ because especially the expensive studies requiring many animals like for carcinogenicity, mutagenicity in vivo and reproductive toxicity are often absent. These effects, if present, would result in the highest $AWARE_2$. As a result, products with a low $AWARE_2$ could contain substances with no or a low hazard or products containing substances which were never tested. However, this is not different from the classification system which is also based on the known hazards. In conclusion, the $AWARE_2$ may not always give a correct indication of the hazards of the product but only of the known hazards.

3. The risk phrase R67 (vapours may cause drowsiness and dizziness) is specifically excluded from the $AWARE_2$ to avoid a double score because this effect is already included in the $AWARE_1$. However, other effects resulting in classification for acute inhalation toxicity of vapours (covered by R20, R23 or R26) and irreversible effects after single inhalatory exposure to vapours (covered by R39/23, R39/26 and R68/20) will also affect the OEL value for the volatile ingredient. Further, R67 is only applied if no classification for acute inhalatory toxicity is required meaning that substances with a high potency for toxicity after inhalation of the vapours do not get classified with R67 but only with R20 or higher. Exclusion of R67 to avoid a double score introduces

inconsistencies with other R-phrases. Further, additional labelling with R67 will result in a low $AWARE_2$ code in most banding systems. Therefore, we propose to include all human health R-phrases in the $AWARE_2$ code system. We propose $AWARE_2$ code number II for preparations additionally labelled with R67 because this is a reversible effect.

4. A table is provided in which R-phrases and some other criteria (pH < 2.0, pH > 11.5 and H+OEL (no R-phrase) are related to $AWARE_2$ code I to V. No substantiation is provided for the choice of 5 classes. Also the substantiation of the choice of the $AWARE_2$ code for each R-phrase is limited to one sentence. Further, some choices are not in line with the classification criteria. For example R33 (Danger for cumulative effects) which is required for substances which are likely to accumulate in the body and may cause some concern which, however, is not sufficient to use R48, is included in AWARE2 code III. However, R48 (harmful) is included in $AWARE_2$ code II. Also it is unclear why pH criteria are included, because the pH of the product is already a criterion for the classification as skin corrosive (R35) but with additional criteria for acid/alkali reserve and testing. Also a classification based on the pH criteria result in a classification with R35 and an $AWARE_2$ of IV whereas a direct comparison of the pH could only result in an $AWARE_2$ of III. The criterion H+OEL (no R-phrase) is not explained in this chapter and therefore difficult to apply. It was clarified by Hildo Krop that H+OEL (no R-phrase) means a substance with an OEL and a skin notation but without an R-phrase for human health. We propose to limit the criteria for the $AWARE_2$ code to the human health R-phrases because the same data used to derive the OEL can also be used for classification. A good justification for the number of $AWARE_2$ code numbers and for the criteria for the different $AWARE_2$ classes would increase the scientific basis of AWARE.

5. Classification of substances and preparations already introduces a major simplification of the toxicological database. This simplification is taken one step further for the $AWARE_2$ code system where the toxicological database is further reduced to 5 classes. Allocation of R-phrases to each band is not a straightforward exercise and depends on expert knowledge. As a consequence, differences between different grouping systems based on classification are unavoidable. This can be seen in the table in Annex I of the AWARE report (Krop et al., 2007) where different grouping systems are compared.
   Several banding systems based on classification have been compared to a quantitative descriptor of the hazard namely the OEL (Scheffers and Wieling, 2005). Even for the hazard banding system with the highest log-linear correlation between hazard-class and OEL only 40% of the OEL variance could be explained by the hazard class. Changing the banding system by increasing the number of bands or changing the band for a particular R-phrase may increase the correlation but is not expected to result in a good correlation between hazard band and OEL. This means that a good quantitative estimate is not possible based only on the classification. Also, it could be questioned whether validation against the OEL is the best validation method for $AWARE_2$ because the $AWARE_2$ not only has to take into account the inhalatory hazards but also the dermal hazards. Therefore, it should be clearly stated that the $AWARE_2$ code number only gives an indication of the hazard. For a better quantitative estimate of the hazard, a different less simplistic approach is required including more toxicological information on the substances present in the preparation. This would require considerable investments by the supplier (see section 3.5 on REACH).
   A European AWARE system based on the classification of the preparation will require a general view on the banding system with a good substantiation of the choices and even then will probably require further negotiation before a European banding system can be agreed. The problem with the classification system is that different types of criteria are used for different endpoints. The criteria for classification are considered the most important starting point for developing a common view on the grouping system. Seen the introduction of the CLP (European Regulation on Classification, Labelling and Packaging of substances and mixtures) regulation in the near future it is proposed to base a banding system for $AWARE_2$ on the CLP criteria (see chapter 4: GHS).

6. The proposed method for the determination of the $AWARE_2$ code as described in the report is unclear. According to the text the $AWARE_2$ is based on the classification of the product. However, it is based on a determination of the classification of the product based on the classification of the individual components according to the flow diagram in chapter 3 of the AWARE document. It was clarified by Hildo Krop that the $AWARE_2$ should only be determined from the classification of the ready-for-use –product. The method for determining the classification by the supplier is the DPD method and a software tool for this is provided (AWARE tool) on the internet. It should be communicated more clearly that $AWARE_2$ is only based on the human health classification of the product, that this should be done according to the method described in the DPD and that a software tool for this is available on the internet.

7. It is stated that the addition rules designed in the DPD have been omitted. It is unclear which rules are omitted, why and what effect this has on the determination of the $AWARE_2$. This was clarified by Hildo Krop as a practical solution for the software problems in the AWARE tool. In principle the DPD method including the addition rules should be used for determining the classification of the final product and from that the $AWARE_2$. This should be communicated more clearly.

8. It is sometimes unclear from the examples provided in chapter 7 how the $AWARE_2$ code is derived. Inclusion of the calculation of the classification and the classification of the preparation into the examples would clarify this.

9. The $AWARE_2$ based on the classification according to the DPD and Annex I could provide a different safety message to the user of the product compared to the lists of substances considered to be carcinogenic, mutagenic or toxic to reproduction as defined under article 4.11 of the 'Arbeidsomstandighedenbesluit'. For example products containing ethanol will have an $AWARE_2$ of I based on the classification of ethanol with F; R11 (highly flammable) only whereas ethanol should be considered as carcinogenic and toxic to reproduction according to the list of the 'Arbeidsomstandighedenbesluit'. This classification would result in the highest $AWARE_2$ code number. It should be clearly stated which classification has to be used for the determination of the $AWARE_2$.
   If the national additions to the list of CMRs for worker protection have to be used then this could introduce a problem to a European introduction of AWARE because different member states have different national CMR lists for worker protection which could potentially lead to differences in AWARE codes between member states.

3.3.3 Conclusion

Overall, we agree with the use of a banding scheme based on the classification of the product according to the DPD for the determination of $AWARE_2$ as an indication of the known hazards of the product. However, the limitations of this approach should be clearly communicated.
Several banding schemes based on the classification are available and are mainly based on expert judgement. Therefore, every banding scheme can be criticised including the scheme proposed in the AWARE report. However, to allow a discussion, the principles and the choices for the proposed banding scheme should be stated and justified.
Such a discussion could be started based on the current proposal or an adjusted proposal based on the current legislation. However, if AWARE will be introduced in Europe then AWARE could better be based on a banding scheme using the CLP classifications (see chapter 4).
The practicalities of the determination of the classification and of the $AWARE_2$ could be described better. Also the examples could be clarified.

3.4 GHS

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3.4.1 Introduction

In the near future the current legislation on classification and labelling of substances and preparations (see section 3.3) will be replaced by a new legislation (Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP)) based on the Globally Harmonised System for classification and labelling of chemicals (GHS) developed by the UN. This system will probably enter into force in 2009 and will fully replace the current system in 2015. The usability of the CLP for the determination of the $AWARE_2$ code is discussed based on the Commision proposal of June 2007 (CLP, 2007).

Derivation of an OEL for $AWARE_1$ in the absence of a derived OEL value is based on the classification of the substance according EC 67/548. When CLP is introduced and EC 67/548 is repealed, a comparable table for the calculation of OEL is required based on the classification according to CLP.

3.4.2 Discussion

Determination of the $AWARE_2$ based on the classification according to the CLP legislation has the same shortcomings and advantages as determination based on the current legislation namely that it is hazard based and not risk based and that the classification is based on available data meaning that a low $AWARE_2$ could be based on the absence of certain effects or on the absence of data. Also there is probably no strict relation between the quantitative hazard (acceptable exposure level) and the hazard banding based on CLP as this relation is also limited for the current system. Therefore, it is proposed to define the $AWARE_2$ as an indication of the known human health hazards.

The criteria for classification under CLP and 67/548 and 1999/45 are mainly comparable and a translation table is present in Appendix VII of the proposed CLP legislation. Table 3.1 in chapter 3 of the AWARE report could be translated based on the translation table. Under CLP the R-phrases are replaced by H-statements (H = hazard) and EU specific EUH-statements. This would result in the following table:

Table 2 Grouping of H-statements into AWARE2 code numbers based on direct translation

$AWARE_2$ code number	H-statements
I	No H-statement for human health effects
II	H332 (R20), H312 (R21), H302 (R22), H304 (R65), H371(R68/20, R68/21, R68/22), H373 (R48/20, R48/21, R48/22), H361f (R62), H361d (R63), EUH066 (R66), H319 (R36), H335 (R37), H315 (R38)
III	H331 (R23), H311 (R24), H301 (R25), H370 (R39/23, R39/24, R39/25), H314 1B (R34), H318 (R41), H351 (R40), H362 (R64), H341 (R68), pH < 2.0, pH > 11.5, EUH029 (R29), EUH031 (R31), H+OEL (no H-statement)
IV	H330 (R26), H310 (R27), H300 (R28), EUH032 (R32), H360F (R60), H360D (R61), H314 1A (R35), H372 (R48/23, R48/24, R48/25), H334 (R42), H317 (R43)
V	H350 (R45), H340 (R46), H350i (R49)

The following table was developed which describes the major criteria for each human health H-statement based on: exposure duration (single versus repeated), type of effect (reversible, irreversible, lethal), potency (dose limits), category, threshold or no threshold and strength of evidence (limited or sufficient) (Table 3). Some of the qualities for an H-statement are derived directly from the criteria but others are a choice by the reviewers based on expert judgement. Some other criteria including the general concentration limit (GCL) for the classification of the preparation, route and the corresponding R-phrase are included as additional information. The last column contains the proposed $AWARE_2$ code number.

Table 3 Classification criteria

H-statement	Category or sub-category	Corresponding R-phrase	Description	Route	Exposure duration	Type of effect	Potency (dose limit)	Threshold	Strength of evidence	GCL	AWARE code
EUH029		R29	Reactivity	Inhalation	Single	Lethality	Contact with water evolve very toxic/toxic gases in dangerous amounts (high potency)	Threshold	Sufficient		V
EUH031		R31	Reactivity	Inhalation	Single	Lethality	Contact with water evolve toxic gases in dangerous amounts (medium potency)	Threshold	Sufficient		IV
EUH032		R32	Reactivity	Inhalation	Single	Lethality	Contact with acid evolve very toxic gases in dangerous amounts (high potency)	Threshold	Sufficient		V
EUH066		R66	Skin effects	Dermal	Both	Reversible	Skin dryness, flaking or cracking but not meeting the criteria for skin irritation	Threshold	Sufficient		II
EUH070		R39-41	Toxic by eye contact	Ocular	Single	Irreversible	Overt systemic toxicity or lethality in an eye irritation study (high potency)	Threshold	Sufficient		V
EUH071			Respiratory tract corrosivity	Inhalation	Single	Irreversible	If classified for acute inhalation toxicity and mechanism by corrosivity or corrosive and not tested for acute inhalation toxicity. Classification potency independent	Threshold	Sufficient		V
H300	1	R28	Acute toxicity	Oral	Single	Lethality	<5 mg/kg bw (high potency)	Threshold	Sufficient	ATE	V
H300	2	R28	Acute toxicity	Oral	Single	Lethality	5 - 50 mg/kg bw (high potency)	Threshold	Sufficient	ATE	V
H301	3	R25	Acute toxicity	Oral	Single	Lethality	50 - 300 mg/kg bw (medium potency)	Threshold	Sufficient	ATE	IV
H302	4	R22	Acute toxicity	Oral	Single	Lethality	300 – 2000 mg/kg bw (low potency)	Threshold	Sufficient	ATE	III
H304	1	R65	Aspiration	Oral	Single	Irreversible	Classification potency independent	Threshold	Sufficient	10%	II
H310	1	R27	Acute toxicity	Dermal	Single	Lethality	<50 mg/kg bw (high potency)	Threshold	Sufficient	ATE	V
H310	2	R27	Acute toxicity	Dermal	Single	Lethality	50 – 200 mg/kg bw (high potency)	Threshold	Sufficient	ATE	V
H311	3	R24	Acute toxicity	Dermal	Single	Lethality	200 – 1000 mg/kg bw (medium potency)	Threshold	Sufficient	ATE	IV
H312	4	R21	Acute toxicity	Dermal	Single	Lethality	1000 - 2000 mg/kg bw (low potency)	Threshold	Sufficient	ATE	III
H314	1A	R35	Skin corrosion	Dermal	Single	Irreversible	Corrosion after 3 minutes of exposure to 0.5 mL (high potency)	Threshold	Sufficient	1%	IV
H314	1B	R34	Skin corrosion	Dermal	Single	Irreversible	Corrosion after 3 minutes to 1 hour of	Threshold	Sufficient	1%	IV

							exposure to 0.5 mL (high potency)				
H314	1C	R34	Skin corrosion	Dermal	Single	Irreversible	Corrosion after 1 to 4 hours of exposure to 0.5 mL (medium potency)	Threshold	Sufficient	1%	III
H315	2	R38	Skin irritant	Dermal	Single	Reversible	Irritation after 4 hours exposure to 0.5 mL	Threshold	Sufficient	3%	II
H317	1	R43	Skin sensitizer	Dermal	Single	Irreversible	Classification potency independent	Threshold	Sufficient	1%	V
H318	1	R41	Eye irritant	Ocular	Single	Irreversible	Irritation (irreversible) after 24 hours exposure to 0.1 mL (low potency)	Threshold	Sufficient	1%	III
H319	2	R36	Eye irritant	Ocular	Single	Reversible	Irritation after 24 hours exposure to 0.1 mL	Threshold	Sufficient	3%	II
H330	1	R26	Acute toxicity	Inhalation	Single	Lethality	Gases: <100 ppm (high potency) Vapours: <0.5 mg/L Dusts and mists: <0.05 mg/L	Threshold	Sufficient	ATE	V
H330	2	R26	Acute toxicity	Inhalation	Single	Lethality	Gases: 100 – 500 ppm (high potency) Vapours: 0.5 – 2.0 mg/L Dusts and mists: 0.05 – 0.5 mg/L	Threshold	Sufficient	ATE	V
H331	3	R23	Acute toxicity	Inhalation	Single	Lethality	Gases: 500 – 2500 ppm (medium potency) Vapours: 2.0 – 10 mg/L Dusts and mists: 0.5 – 1.0 mg/L	Threshold	Sufficient	ATE	IV
H332	4	R20	Acute toxicity	Inhalation	Single	Lethality	Gases: 2500 – 20000 ppm (low potency) Vapours: 10 – 20 mg/L Dusts and mists: 1.0 – 5.0 mg/L	Threshold	Sufficient	ATE	III
H334	1	R42	Respiratory sensitizer	Inhalation	Single	Irreversible	Classification potency independent	Threshold	Sufficient	1%	V
H335	3	R37	Respiratory tract irritant	Inhalation	Single	Reversible	Lung irritation after single exposure	Threshold	Sufficient	20%	II
H336	3	R67	CNS depression	All	Single	Reversible	CNS depression	Threshold	Sufficient	20%	II
H340	1A/1B	R46	Mutagen cat. 1/2	All	Single	Irreversible	Classification potency independent	Non-threshold	Sufficient	0.1%	VI
H341	2	R68	Mutagenicity	All	Single	Irreversible	Classification potency independent	Non-threshold	Limited	1%	V
H350	1A/1B	R45	Carcinogen	All	Repeated	Irreversible	Classification potency independent	Non-threshold	Sufficient	0.1%	VI
H350i	1	R49	Lung carcinogen	Inhalation	Repeated	Irreversible	Classification potency independent	Non-threshold	Sufficient	0.1%	VI
H351	2	R40	Carcinogen	All	Repeated	Irreversible	Classification potency independent	Threshold	Limited	1%	IV
H360D	1A/1B	R61	Reprotoxic (development)	All	Repeated	Irreversible	Classification potency independent	Threshold	Sufficient	0.3%	V

H360F	1A/1B	R60	Reprotoxic (fertility)	All	Repeated	Irreversible	Classification potency independent	Threshold	Sufficient	0.3%	V
H361d	2	R62	Reprotoxic (development)	All	Repeated	Irreversible	Classification potency independent	Threshold	Limited	3%	IV
H361f	2	R63	Reprotoxic (fertility)	All	Repeated	Irreversible	Classification potency independent	Threshold	Limited	3%	IV
H362	1	R64	Effect on or via lactation	All	Repeated	Reversible, irreversible or lethal	Classification potency independent	Threshold	Sufficient	0.3%	V
H370	1	R39/23 R39/24 R39/25 R39/26 R39/27 R39/28	Acute toxicity (non lethal)	All	Single	Irreversible	gases: <2500 ppm (medium potency) vapour: <10 mg/L aerosol: <1 mg/L dermal: <1000 mg/kg bw oral: <300 mg/kg bw	Threshold	Sufficient	10%	IV
H371	2	R68/20 R68/21 R68/22	Acute toxicity (non lethal)	All	Single	Irreversible	gases: 2500 – 20000 ppm (low potency) vapour: 10-20 mg/L aerosol: 1-5 mg/L dermal: 1000 – 2000 mg/kg bw oral: 300 – 2000 mg/kg bw	Threshold	Sufficient	10%	III
H372	1	R48/23 R48/24 R48/25	Repeated dose toxicity	All	Repeated	Irreversible	oral: <10 mg/kg bw/day (90 days) dermal: <20 mg/kg bw/day (90 days) gas: <50 ppm, 6 h/day (90 days) vapour: <0.2 mg/L, 6 h/day (90 days) aerosol: <0.02 mg/L, 6 h/day (90 days) (medium potency)	Threshold	Sufficient	10%	IV
H373	2	R48/20 R48/21 R48/22	Repeated dose toxicity	All	Repeated	Irreversible	oral: 10 - 100 mg/kg bw/day (90 days) dermal: 20 - 200 mg/kg bw/day (90 days) gas: 50 - 250 ppm, 6 h/day (90 days) vapour: 0.2 - 1.0mg/L, 6 h/day (90 days) aerosol: 0.02 – 0.2 mg/L, 6 h/day (90 days) (low potency)	Threshold	Sufficient	10%	III

The following criteria were used to classify the different criteria into $AWARE_2$ code numbers:

- Reversible effects < irreversible = reversible and irreversible = lethal (all stated as irreversible in Table 3).
- Low potency < medium potency < high potency = classification potency independent.
- Limited evidence < sufficient evidence (only discriminative for CMR endpoints).
- Threshold < non-threshold.

Overall this leads to 6 $AWARE_2$ code numbers instead of 5 and the following table:

Table 4 General criteria for the grouping of H-statements into $AWARE_2$ codes.

$AWARE_2$ code	H-statements
I	No H-statements for human health
II	reversible effects, threshold, sufficient evidence, all potencies
III	irreversible, threshold, sufficient evidence, low potency
IV	irreversible, threshold, sufficient evidence, medium potency irreversible, threshold, limited evidence, classification potency independent
V	irreversible, threshold, sufficient evidence, high potency irreversible, threshold, sufficient evidence, classification potency independent irreversible, non-threshold, limited evidence, classification potency independent
VI	irreversible, non-threshold, sufficient evidence, classification potency independent

Based on the classification criteria and the general grouping provided in the table above the different R-phrases can be grouped as shown in the table below:

Table 5 Grouping of H-statements into $AWARE_2$ codes.

$AWARE_2$ code	H-statement
I	No H-statement for human health
II	EUH066, H304, H315, H319, H335, H336
III	H302, H312, H314 (1C), H318, H332, H371, H373
IV	EUH031, H301, H311, H314 (1A/1B), H331, H351, H361f, H361d, H370, H372
V	EUH029, EUH032, EUH070, EUH071, H300, H310, H317, H330, H334, H341, H360D, H360F, H362
VI	H340, H350, H350i

However, exceptions on the general criteria in Table 3 were made for the following H-statements:

H304 (aspiration).
This is a potentially lethal effect with a threshold and the classification is based on sufficient evidence without limitations on potency. Using Table 4, this would result in an $AWARE_2$ code number of V. However, a certain amount of these type of liquids is required in the lungs before the effects can occur. This is only expected after oral exposure. This is not a relevant route for worker exposure. Therefore, a lower $AWARE_2$ number code for this effect is considered correct for workers. We propose to use $AWARE_2$ code number II for H304.

H314 (Skin corrosion)
This is an irreversible effect with a threshold and the classification is based on sufficient evidence. The potency is not based on the amount required for the effect but on the duration of exposure before the irreversible effect is observed and a fixed concentration per cm^2. Corrosion after exposure up to

3 minutes and up to 1 hour was chosen as high potency and between1 and 4 hours as medium potency. Further, the irreversible effect is only local and mainly esthetical. Therefore, this effect is considered less hazardous then other irreversible effects and a lower $AWARE_2$ code number is used (one code number lower).

H362 (Effects on or via lactation)
Classification of effects on or via lactation can be based on reversible effects but also on irreversible effects. This difference would have a strong impact on the $AWARE_2$ code number. However, this distinction cannot be made based on the classification. Therefore, a worst case approach is used assuming that the effects are always irreversible. This results in an $AWARE_2$ code number of V.

The proposed relation between the $AWARE_2$ code numbers and the H-statements for human health differ only to some degree from the proposal based on direct translation. Other information on the preparation like pH is not included because the pH would directly result in a certain classification for corrosivity. The proposed banding scheme is based on a number of criteria and choices for different H-statements. Therefore, other EU member states could have different opinions on the best banding scheme. As a result, discussions on a mutual banding scheme can be expected if AWARE is introduced in Europe.

The proposed banding of the hazard-statements could be 'validated' for the inhalatory route by comparing the OEL values of a large number of substances with the $AWARE_2$ code number. However, it has to be taken into account that validation for substances may not be simply extrapolated to mixtures because for mixtures also the general concentration limit have to be taken into account. Also it could be questioned whether validation against the OEL is the best validation method for $AWARE_2$ because the $AWARE_2$ not only has to take into account the inhalatory hazards but also the dermal hazards. Validation could be done for substances with an OEL value based on aerosols because the substances with OELs based on vapour are already covered by the $AWARE_1$. Overall, validation of the hazard banding system based on CLP is not recommended because a limited correlation is expected as was found for other hazard banding systems. However, if such a validation is required it could be discussed whether this validation should be done for the current proposal or for a mutual European banding scheme.

The GHS will be updated every two years. Therefore, the CLP regulation will probably also be updated every two years. As a result, the banding of the hazard statements for $AWARE_2$ may have to be adapted every two years. For example, sub categorization for sensitisation is currently discussed at the UN level. It has to be decided whether both subcategories will have the same $AWARE_2$ code number.

3.4.3 Conclusion

The classification according to the CLP regulation can be used to determine the $AWARE_2$ in the same way as for the current legislation and has the same limitations as hazard banding based on the current legislation namely, that it is not precise and only based on known hazards. The banding of the hazards can be done in several ways as has been done in the past for the current system without objective criteria for the best method. Therefore, discussions on the banding for $AWARE_2$ can be expected if AWARE is introduced in Europe.

3.5 REACH

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3.5.1 Introduction

In the process of developing AWARE, the new chemicals legislation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) came into force in Europe (EU, 2007). REACH requires 'safe use' of chemical substances, either on their own, in preparations or in articles, i.e. manufacturers, importers and downstream users may only manufacture/place on the market/use substances in such a way that the risks associated with these substances for human health and the environment are controlled.
This part of the report deals with the relationship between AWARE and REACH. After a short introduction on REACH, a comparison of the main characteristics of AWARE and REACH will be given, as well as an indication of the possibilities of AWARE providing information for REACH, and vice versa. After this inventory, it will be evaluated whether there can be a role for AWARE under REACH.

3.5.2 REACH

REACH is based on the principle that human health and the environment[1] may not be adversely affected by the manufacture, import, use or placing on the market of a substance. To this end, REACH sets out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are controlled during manufacture and their own use(s) and that others further down the supply chain can control the risks (EU, 2007; ECHA, 2008a). For this purpose, a chemical safety assessment (CSA) needs to be prepared for each substance manufactured or imported in a quantity of 10 tonnes or more per year, with the aim:

- to assess the intrinsic hazards of a substance, including the determination of the appropriate classification and labelling and, where possible, the derivation of no-effect-levels (Derived No-Effect Levels, or DNELs);

and, when the substance is classified as dangerous,

- to assess the exposure of humans resulting from manufacture and uses throughout the life cycle of the substance, including the generation of sufficiently detailed information on uses, use conditions and emissions/exposures of the substance;
- to characterise the risks following such exposure;

and, ultimately,

- to identify and document the conditions of manufacture and use which are needed to control the risks to human health in an exposure scenario (ES), which includes operational conditions (OCs; for example duration and frequency of use, amount or concentration of a substance in an activity, process temperature) and risk management measures (RMMs; for example local exhaust ventilation, wearing certain types of gloves). Risks are regarded controlled when the estimated exposure levels do not exceed the DNELs (ratio exposure/DNEL should be <1).

The CSA needs to be documented in the chemical safety report (CSR). Furthermore, relevant information from the CSR (DNELs and, when developed, ESs) needs to be transferred/ annexed to the safety data sheet (SDS). This in order to communicate down the supply chain the conditions of use (the OCs and RMMs) ensuring control of risk.

[1] Environment is not of relevance for this report item, and is therefore not further adressed.

3.5.3 Comparison AWARE – REACH

The REACH Regulation has a requirement for all substances manufactured/imported in a quantity ≥ 10 tonnes/year to control the level of exposure to below the DNEL, indicating control of risk ('safe use'). AWARE, on the other hand, is (at the moment) not a legal requirement but a voluntary coding system that can be used as a tool to reduce the exposure to certain substances (for example VOCs), aiming thus at 'safer use'.
The AWARE methodology provides a risk indicator for the ready-for-use product at the level of the Occupational Exposure Limit (OEL) (or the combined OEL, in case of more than one VOC in the product), addressing one standardized, theoretical exposure scenario for the VOC(s) in the product. REACH, however, deals with risks on a substance-basis, addressing the exposure in as many ESs as considered necessary to cover the manufacturing process and all identified uses throughout the life cycle of the substance. The ES not only provides an exposure estimate, but also a documentation of the underlying OCs and RMMs.
For control of risks further down the supply chain, REACH requires that all relevant information (such as DNELs and ESs) is communicated via the extended SDS. Although the AWARE code is also to be communicated towards the end user, it is not clear whether communication will be via the product label, or via the SDS. [NB: in case of the former, AWARE would probably better relate to the future new EU legislation on classification, labelling and packaging of substances and mixtures (CLP) than to REACH.]

3.5.4 Can AWARE provide information for REACH?

One of the characteristics of AWARE is that it uses publicly available information. This information is also available for REACH, independent of AWARE. So, in a general sense, there is little added value of AWARE.

Exposure information
The data necessary for exposure estimation in the AWARE methodology are far too limited to build ESs under REACH. Moreover, AWARE does not take into account OCs and RMMs when estimating exposure, whereas this is required for REACH. Another reason why it is difficult to feed in AWARE exposure information into REACH is that AWARE deals with only one standardized, theoretical exposure scenario, whereas for REACH the exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses.

Harzard information
The OEL(s) necessary for AWARE1 can under certain circumstances be used as DNEL(s) under REACH. Crucial is that employers (regardless if they are registrants or downstream users under REACH) are responsible for compliance with all legislations in force, i.e. both REACH and the worker protection legislation. Consequently, after specifying the different types of OELs, the guidance sets out what to do in developing DNELs when such OELs are available for a substance (ECHA, 2008a). In summary:
On EU-level, there can be Indicative OELs (IOELs) or Binding OELs (BOELs). IOELs are health-based, non-binding values, BOELs are binding values that are not only health-based, but also reflect socio-economic and technical feasibility factors. EU IOELs and BOELs have to be transposed into national legislation. Depending on national legislation and practices , the national IOEL can be higher or lower than the EU IOEL. The national BOEL, however, can be lower than the EU BOEL, but not higher.

On a national level, Member States may set national OELs for other substances than those included in Community legislation. Some of these national OELs are purely health-based, others may also reflect feasibility factors[2]. In most Member States the national OELs (including the transposed IOELs and BOELs) are legally binding.
In order to be in compliance with REACH, the guidance sets out that:

- for any substance with an OEL, the scientific background (approach used, toxicological information available and evaluations of health effects) for setting the OEL should be evaluated and compared to the scientific information required for fulfilling the obligations under REACH and to the approach described in the guidance for deriving DNELs;
- any differences in approach or information should be taken into account in order to assess whether the OEL provides the appropriate level of protection required by REACH;
- if that is the case, the OEL may be used as a DNEL for the same exposure route and duration;
- if that is not the case, a DNEL should be derived, whilst also taking account of the scientific information that was used for setting the OEL.

Given that employers also have to comply with the worker protection legislation, this can be interpreted to mean that the lowest one shall be used to ensure full compliance with both legislations. In other words, when the derived DNEL is lower than the legally binding national OEL for the same exposure route and duration, this OEL cannot be used in place of the DNEL. Only when the derived DNEL is equal to or higher than the national OEL for the same exposure route and duration and when the national OEL is legally binding, the OEL may or shall, respectively, be used in place of the DNEL. Importantly, the 'default OEL' presented in AWARE as an option in case no specific OEL is available for a substance and which is to be based on the health hazard labelling of that substance and its vapour pressure, will not be acceptable for REACH and cannot be used as DNEL.

The hazard banding scheme to determine the value of $AWARE_2$ is based on arrangement of the R-phrase(s) assigned to the ready-for-use product (according to the DPD (EC, 1999)) into five different categories/hazard bands. The Roman figures for $AWARE_2$ express an increase in hazardous potential from I to V, but only in a qualitative way, simply because the classification criteria for the different human health effects in the DSD (EEC, 1967) and the DPD are, for the major part, not based on potency. This qualitative information is of limited use under REACH, because REACH in principle requires a quantitative risk indication, based on the exposure estimate belonging to an ES and the DNEL representative for that ES. Potency is accounted for, since this DNEL has to be the most critical one, for the leading health effect.
For substances manufactured/imported in quantities of <10 tonnes per year, however, no DNEL has to be derived under REACH. For these lower tonnage substances the use of hazard banding based on R-phrases could be an option. But it is questionable whether for these substances there will be R-phrases, because classification depends on availability of data (which will be limited for the lower tonnage substances under REACH) and only relates to known hazards (see chapters 3.3 and 3.4). Moreover, in order to be used under REACH, there has to be agreement in Europe on the hazard banding scheme to be used.

[2] Consequently, national OELs may differ for a particular substance.

3.5.5 Can REACH provide information for AWARE?

$AWARE_1$

The basis for $AWARE_1$, representing the estimated potential risk of the exposure to vapour from the VOC(s) in the ready-for-use product, is formed by:

- the OEL(s) for the VOC(s) in the product, and
- a few substance and product-specific (physico-chemical) parameters, allowing a simple, standardized, theoretical exposure estimation for the VOC(s) in the product.

At this point in time, not for all (volatile) substances an OEL is available. On EU-level, there are IOELs for approximately 100 substances and BOELs for 4 substances, all of which have been transposed into national legislation. On a national level, various Member States have set national OELs for approximately another 600 substances. So, for those substances not having an OEL, REACH will (in time, and provided the substance is manufactured/imported in a quantity of ≥ 10 tonnes per year) provide useful information for setting a health-based value. In most cases this will be a value derived for repeated exposure, because the guidance on REACH indicates that the default is a DNELlong-term (comparable to an 8-hr TWA OEL). Only in incidental cases, for example if an acute toxicity hazard (leading to classification) has been identified and there is a potential for high peak exposures, a DNELacute (comparable to for example a 15-min STEL) will have to be derived (ECHA, 2008a). Importantly, the DNEL derived will provide a better estimate of the OEL for a substance not having an OEL than the 'default OEL' presented in AWARE, which is to be based on the health hazard labelling of that substance and its vapour pressure.

The limited data needed for the exposure estimation (composition of product, density of product, weight percentage of individual components, vapour pressure of volatile components) can be found in the public domain, available through common product information and SDSs. The SDSs provided under REACH can of course serve as data source for $AWARE_1$ (by the end of May 2018 SDSs will be availabe for all registered substances, i.e. all substances manufactured/imported in a quantity ≥ 1 tonne/year), but the detailed information in the ESs in the extended SDSs is not necessary.

$AWARE_2$

The basis for $AWARE_2$, providing a hazard indication for the ready-for-use product, is formed by the R-phrase(s) assigned to that product and subsequent categorization of these R-phrase(s) in hazard bands.

One of the objectives of REACH is to determine the classification of a substance in accordance with the DSD (EEC, 1967). In the near future, this Directive and the DPD (EC, 1999) are going to be replaced by a new EU legislation (Regulation on Classification, Labelling and Packaging of substances and mixtures; CLP). However, the criteria for classification under CLP are for the most part comparable to those under DSD and DPD. So, in principle, information provided under REACH can be used to determine the classification of the individual substances in a product. REACH, however, does not specifically address classification of products. But one can in principle combine the R-phrase(s) for the individual components with information on the content of the individual substances in the product, so that the product can be classified in accordance with the DPD.

3.5.6 Could AWARE play a role under REACH?

Arguments in favour of AWARE are that the methodology is based on a relatively simple algorithm, which makes use of only a few substance and product specific parameters that can easily be found in the product information or in publicly available literature. Moreover, AWARE provides a risk indicator for the ready-for-use product, which in principle should facilitate a comparison between products and can help in selecting the lowest hazardous product (the lower the AWARE code, the lower the hazardous properties of the product). This comparison is far easier than under REACH, although there is some guidance on how to deal with preparations (ECHA, 2008b). Under REACH, one has to first collect the (extended) SDSs for the relevant info on the different substances in the product, i.e. the exposure estimate belonging to an ES and the DNEL representative for that ES. This provides the risk indicators for the individual substances, i.e. the ratio exposure/DNEL (which should all be <1, otherwise no 'safe use'). Then, one has to combine these individual substance risk indicators to a risk indicator for the product. A possibility could for instance be to sum up the individual substance risk indicators; in order to guarantee 'safe use', the combined risk indicator for the product should in principle then also be <1.

One drawback of the AWARE methodology is that it is not clear how $AWARE_1$ (a quantitative value) relates to $AWARE_2$ (a qualitative value, not covering the potency of the substances in the product) and how to weigh them against each other. For example, how to make a choice between a product with relatively low $AWARE_1$/high $AWARE_2$ values and a product with relatively high $AWARE_1$/low $AWARE_2$ values?
Account should also be given to the following. AWARE provides a risk indicator at the level of the OEL (in case of one VOC per product) or the combined OEL (in case of more than one VOC per product). As such, it is reckoning with worker protection legislation, but not necessarily with REACH. Besides, where the guidance on REACH provides a well documented way of deriving DNELs, not all OELs have been derived in a uniform, transparent way. Furthermore, AWARE provides a risk indicator for only one standardized, theoretical exposure scenario. Whereas this indeed facilitates comparison between products, this does not account for uses other than accounted for in the standardized exposure scenario. For example, when product innovation leads to a product with a lower AWARE code, but this product has to be applied more frequently or at a higher volume to get the same result, this use pattern is not covered under AWARE whereas under REACH it will be.

In conclusion, since REACH already takes care of 'safe use' of substances, there seems to be little added value in AWARE. REACH might be more complex with respect to data requirements (on toxicological effects and exposure, including OCs and RMMs) and DNEL derivation), but can just like AWARE be used in the selection of less hazardous products. Within a company, the selection of ready-for-use products is normally up to the person in charge of purchasing and/or the management, in consultation with the occupational hygienist. These persons should also be able to handle the information governed under REACH (for example DNELs and ESs). And although REACH already guarantees 'safe use' of a substance when the conditions (OCs and RMMs) described in the ES are adhered to, there will be differences between substances in the ratio exposure/DNEL and in the conditions ensuring the 'safe use'. This information should enable the persons in charge to choose, among the 'safe' substances, for substances that have a bigger margin between exposure and DNEL or that require 'lighter' OCs and RMMs.
Yet, it is realized that it will take until 2018 before REACH effectively provides the essential information for all substances manufactured or imported in quantities above 1 tonne per year. So, AWARE might be a useful tool to reduce the risk for organic solvent neurotoxicity in occupational settings in the meantime. It is also realized that there is little guidance on how to deal with preparations under REACH, where formulators will have to prepare an ES (in the SDS) for their preparations based

on the ESs for the individual components. Unfortunately, it will take many years before the ESs for all relevant substances will be available, due to the gradual phase-in of existing substances in REACH. The experience gained in the AWARE project with preparations might therefore be useful in guiding formulators in how to deal with preparations and in monitoring the progress in this area.

3.5.7 Conclusion

By means of a relatively simple methodology, AWARE integrates data on the individual components of a preparation into a risk indicator (i.e., the $AWARE_1$–$AWARE_2$ code) for the endproduct. As such, AWARE in principle provides an easy tool for comparison of the hazardous properties of products. The coding system, however, is valid only for one standardized, theoretical exposure scenario; it does not cover all use patterns of the product. Besides, the relation and weighing between $AWARE_1$ and $AWARE_2$ are unclear.
Given the pros and cons of AWARE, whilst noting at the same time that REACH already takes care of 'safe use' of substances and that the information governed under REACH will also make it possible to compare products, it seems there is little added value in AWARE. Yet, given the gradual phase-in of existing substances in REACH, it will take years before the essential information becomes available for all substances. The methodology of AWARE and the experience gained with it might therefore be useful in the meantime.

3.6 Comparison of AWARE with similar tools

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3.6.1 Introduction

AWARE is designed to support decision making in choosing of safer products by classifying possible health risks associated with the use of the products and for the development of safer products. To this end, hazard and exposure ranking systems have been developed and combined in the AWARE tool. Below, an inventory of available tools with a general purpose (partly) comparable to AWARE has been made (see Appendix 2). This comparison of tools is limited to $AWARE_1$. A number of instruments for potential comparison with $AWARE_1$ has been selected, based on a prior inventory of tools, made by TNO in the scope of the 'VASt' programme (in 2004), extended with tools that became known to the authors since that time. No full search for potential tools was done in this project. In the Appendix 2, also the relevance of comparing them with $AWARE_1$ in more detail is indicated. Tools have been judged as (possibly) relevant if, at a first glance, a hazard, exposure and/or risk assessment element is included in the tool, other than a local (RI&E) assessment. Some tools that are very similar to other tools were not specifically evaluated, but are mentioned in this document for comparison. Since AWARE is based on the concepts of the Norwegian OAR and Danish MAL code (Krop et al., 2007), the concept and form of the AWARE is strongly comparable. OAR and MAL are therefore not further discussed in this section.

In this comparison of tools, both the element of hazard banding as well as exposure estimation are considered. For hazard banding parts, the different tools either use OEL values (sometimes indirectly based on hazard banding based on R-phrases) or R-phrases.
For the comparison of hazard banding parts of the tools directly based on R-phrases, it is referred to the conclusion of section 3.2.4. This reads that several banding schemes based on the classification are available and are mainly based on expert judgement. Therefore, every banding scheme can be criticised

including the scheme proposed in the AWARE report. However, to allow a discussion, the principles and the choices for the proposed banding scheme should be stated and justified. The latter is not the case.

3.6.2 Overview of similar tools

$AWARE_1$
$AWARE_1$ contains a structured assessment of the substance/product related emission potential, based on evaporation. The $AWARE_1$ code is the result of a simplified static approach based on the evaporation of VOC from the product after use taking into account the initial product composition. The outcome is expressed as the amount of m^3 fresh air, required to ventilate 1 m^3 of the working space, to dilute the evaporated volatiles after applying 1 liter of VOC containing product, at a room temperature of 20 ^oC and an atmospheric pressure of 10^5 Pa, emitted from the surface of the treated object, which may lead to exposure of the worker, without adversely effecting the health of the worker.
The final parameter is not only based on content and evaporation factor (based on Raoults law), but also on the OEL of the substance or the indicative value resulting from hazard banding. It is not a real exposure estimate, but a relative risk parameter. The exposure part describes the relative emission potential of substances from products by using a standardised calculation, independent of the actual exposure situation.

Hereafter the tools that were evaluated in more detail are briefly described.

COSHH Essentials
The toolkit is designed to assist small and medium sized enterprises in their control of chemical risks. It consists of a hazard banding, exposure banding and resulting risk banding section. Dependent on the risk band the user is guided to a number of "control sheets". There are generic control sheets for general control strategies and more specific control sheets for specific types of activities. COSHH essentials is a toolkit designed for use with individual substances, not for products.

Hazard banding within COSHH essentials is based on R-phrases. For exposure banding, the ability to become airborne is based on the physico-chemical characteristics of the substance. For liquids, three levels of volatility are used, based on vapour pressure: low (< 500 Pa), medium (500-25,000 Pa) en high (> 25,000 Pa). It is also possible to classify the liquids based on their boiling point: low (boiling point <= 2 x process temperature + 10), medium (boiling point between 2 x process temperature + 10 and 5 x process temperature + 50) and high (boiling point >= 5 x process temperature + 50). No correction for percentage of substance in a product is taken into account. For solids, the ability to become airborne is based on dustiness (low = pellets, medium = crystals or granules, high = powders). Finally, COSSH essentials combines the outcome of the hazard and the exposure banding in a matrix, resulting in the 'risk band' indicated above.

UIC DT 63 and UIC DT 80
The 'Document Techniques' number 63 and 80 of the French 'Union des Industries Chimiques' describe a method to assist companies in evaluating the risks of individual chemicals, not products. DT 80 is the most recent version (2004) and intends to provide tools in line with the EU Chemical Agents Directive (98/24/EC) and the EU Directive on carcinogens and mutagens (2004/37/EC). DT 80 describes a screening level and a semi-quantitive level of risk assessment and refers to quantitative

assessment as the third level. The screening level contains hazard banding, exposure banding and risk banding, similar to COSHH Essentials.

The ability to become airborne in UIC DT 80 is based on physico-chemical characteristics and is classified in three classes. For liquids it is based on the vapour pressure: low (< 100 Pa), medium (100-7000 Pa) and high (> 7000 Pa). For solids it is based on 'dustiness': low (solids that can sublimate or pulverize or have a particle size below 5 μm), high (solids that do not sublimate or pulverize or have a particle size of more than 25 μm) and medium (all other solids). No correction for percentage of substance in a product used is indicated.

GISCODES and Product Codes

The German 'Berufsgenossenschaft Bau' presents a system of product information in a website 'WINGIS online'. Building chemicals in this system are characterized based on the percentage of certain (toxic) substances, their classification and labelling and their flammability. For 13 different larger product groups (for example 'epoxy resins') a number of groups is classified (for example. 'sensitizing epoxy resin product without solvents' or 'sensitizing epoxy resin product low solvents'). For each larger group percentages of specific types of substances can be the basis for classification. For epoxy resins it is for example 'solvents', defined as volatile organic compounds with a boiling point below 200 ºC, while for releasing agents both the solvent content (in this case defined as volatile organic compounds with a boiling point below 250 ºC) and the content of aromatics (not clearly defined) are used as criterion. With each product group (generic) safety data sheets and information on safe handling are provided. This includes a pictorial presentation of the level of dermal, inhalation and fire hazard by means of a green to red colored bar. Red indicates high hazard and green low hazard. An indicator on the bar shows the (relative) hazard of the product group. The relative hazards are shown separately for manual application and spray application. This indicates that exposure aspects play a role in the relative hazard assessment.

Probably a differentiation based on vapour pressure is made for the ability to become airborne. Within the Wingis system or the descriptions of GISCODES and Product codes no details are provided on how this evaluation of relative hazard is done. Because the system refers to the German 'Technische Regeln für Gefahrstoffe' in several places, it is possible that the relative hazard is based on the so-called 'division model' (Spalten Modell). In that case exposure banding is based on vapour pressure (for liquids) with the following classes: very low (< 200 Pa), low (200-1000 Pa), medium (1000-5000 Pa), high (5000-25000 Pa) and very high (>25000 Pa).

The system of GISCODES and Produce codes with the pictorial representation of relative hazard can be used to compare products.

ECETOC TRA

ECETOC TRA is a tool to do a first tier (screening) risk assessment of chemicals (not products). It can e.g. be used for regulatory risk assessment purposes. It includes a hazard banding section based on classification, leading to indicative limit values, and an exposure model. The exposure model leads to a quantitative exposure estimate, based on ability to become airborne of the product, use scenario, use of local exhaust ventilation and duration of exposure. For liquids the exposure model contains a classification of ability to become airborne based on vapour pressure into three classes: low (< 1000 Pa), medium (1000-10,000 Pa) and high (> 10,000 Pa). No correction for percentage of substance in a product is indicated. The risk assessment is done by comparing the exposure estimate with a limit value or with the indicative limit value resulting from the hazard banding.

Classification for shoe repair products
The tool was designed to assist in the choice of shoe repair products based on the hazard and relative emission potential. The tool is based on the OAR system, a predecessor of $AWARE_1$, and is therefore very similar to AWARE. For this reason, the tool is not further discussed.

ILO Chemical Control Toolkit
The toolkit is designed to identify control solutions, not to rank chemicals or chemical products. Nevertheless, it can be used to compare chemical substances and hazard and exposure banding systems have been included in the tool. COSHH Essentials has been used as a model for developing the toolkit.

The ability to become airborne is based on the physical form of the chemical. For liquids, three levels of volatility (high, boiling point <50 ^{o}C; medium, 50 ^{o}C<boiling point<150 ^{o}C; low, boiling point >150 ^{o}C) were chosen for tasks carried out at room temperature. No correction for percentage of substance in a product is taken into account. For tasks carried out above room temperature, a graph is provided were the user can categorise the volatility (high, medium, low) based on the combination of boiling point and operating temperature.
For a group of common solvents, hazard groups and volatility can be read off a table provided in the tool.

PISA
PISA is a tool to generate information sheets on use and safe handling of chemicals in building materials/products. The tool does not include hazard or exposure banding systems. Ranking of product may be done by manual comparison of information sheets.

DOHSBase
DOHSBase can be used for ranking of chemical substances, not products, for prioritisation in terms of risk management. In DOHSBase, several hazard banding systems have been included (amongst others. COSHH Essentials, TRGS 440) and it is up to the user to select one. The authors express a preference for the TRGS 440 proposal, because it included the most recent update of Annex I of Directive 67/548 at the time of publication of the tool. Also, the TRGS 440 proposal in an analysis appeared to fit better to real occupational exposure limits of a few hundred substances than for example the COSHH Essentials hazard banding.
DOHSBase is a tool for ranking pure chemicals instead of products. Consequently, the concentration in the product is not a variable in the calculation of the 'ability to become ariborne'. In DOHSBase, the vapour pressure is used to calculate the maximal concentration of a chemical in air. The possible presence of chemical resulting from the presence of aerosols or disturbance of the liquid surface layer is not included. Like in AWARE, the maximal concentration of a chemical in air is weighed against the available occupational exposure limit to get an index of exposure.

3.6.3 Discussion and conclusions

$AWARE_1$ is a product code based on three elements of the substances in the product: the ability to become airborne (related to vapour pressure), the concentration of substance in the product and the occupational exposure limit (OEL) or indicative limit (based on hazard banding). It facilitates easy comparison of products; a lower value indicates a lower risk product. Only few other tools were found that actually serve the same purpose directly, i.e. the Dutch classification system for shoe repair products, the Dutch PISA system, and the German GISCODES/Product codes system.

The classification system for shoe repair products is closely related, because it has the same purpose (comparison of products) and a very similar method. A predecessor of $AWARE_1$ (OAR) is used in this system. It could not be easily clarified why $AWARE_1$ was not used. Because of the very similar nature of OAR and $AWARE_1$, no specific evaluation for this classification system is made.
There are (at least) two systems for product classification or product information on building chemicals, i.e. the Dutch PISA system and the German GISCODES/Product codes system.
The Dutch PISA system does not contain a relative risk evaluation. The only way to compare products is to see whether one product needs less stringent controls than another.
The German GISCODES and Product codes are a coding system for building products. A direct comparison between the two tools is presented in Table 6. It can be concluded that both tools serve the same purpose, but use a different approach. The differences relate to both the hazard part (OEL versus R-phrases) as well as the exposure part (linear versus categorical approach).

Table 6 Comparison between $AWARE_1$ and GISCODES/Product codes

Element	$AWARE_1$	GISCODES/Product codes
Scope	All products with (volatile) liquids	Building chemical products
	Separate products	Product (sub-)groups
Hazard aspect	OELs or indicative limit values based on hazard banding	Classification and labeling (R-phrases)
Concentration of substance in product	Linearly taken into account	In classes; different classes for different product groups
Ability to become airborne	Linearly related to vapour pressure (between lower and upper boundary)	Not specifically taken into account; indirectly by only taking relevant product types in account
Risk assessment	Equation calculating the code, taking into account hazard, concentration and ability to become airborne quantitatively	Not fully clear; possibly via TRGS 440 method (hazard and exposure banding leading to risk bands)

Next to tools that directly or indirectly aim at comparison of products, there are a number of tools that contain elements comparable to the hazard or exposure part of $AWARE_1$. Several exposure models take account of ability to become airborne and concentration of substance in the product. Stoffenmanager (Marquart et al., 2008 and Tielemans et al., 2008), for example uses the same equation as $AWARE_1$ for taking account of concentration of substance in the product and vapour pressure. DOHSBase uses the vapour pressure in a linear equation for estimating ability to become airborne. Other models, such as EASE (Tickner et al., 2005) use banding systems for vapour pressure.

The exposure banding part of tools that do not use vapour pressure in a linear equation generally contain between three to five classes of vapour pressure or boiling point to classify availability to become airborne. Each tool uses its own borders between classes and none of the references studied clearly explains why these specific borders are used.

The different hazard banding parts of different tools either use OEL values (sometimes indirectly based on hazard banding based on R-phrases) or R-phrases.

ECETOC TRA is a tool that uses exposure banding and OELs or hazard banding to come to quantitative risk assessment. Other tools use exposure banding and hazard banding (combined to risk

banding) to do a screening risk assessment. Examples are UIC DT 80 and a similar French tool by Vincent et al. (2005) as well as the German TRGS 440 'Spalten Modell' that are not specifically described here. A few similar tools use risk banding to guide the user towards general or specific control strategies. Examples are COSHH Essentials and the ILO Chemical Control Toolkit.

Generally, the tools compared here with $AWARE_1$ are aimed at one substance at a time. The exceptions are PISA and GISCODES/Product codes. In most cases the tools do not provide a formal method to account for percentage of substance in a product.

Comparing with the other tools, $AWARE_1$ has a number of advantages, specifically for the exposure estimation part:

- Aimed at liquid products in general
- Structured and consistent method to take account of concentration of substance in the product and of vapour pressure
- Clear algorithms
- Higher apparent discriminatory power than banding tools
- Results in easily understandable resulting codes; lower = better

On the other hand, the fact that $AWARE_1$ uses clear algorithms, has a high apparent discriminatory power and uses easily understandable codes may provide an unwarranted sense of accuracy, possibly leading to unfounded decisions (for example to change from a product with code 43 to one with code 41).

The PISA and GISCODE/Product code systems are more than just a classification system. They provide advice on safe handling too. $AWARE_1$ does not provide such advice and is mainly used to guide the sales of products.

Overall it can be considered that $AWARE_1$ has added value over the other systems as a product classification system, but the other systems have added value in other areas, such as advice on risk management.

4 Conclusion

AWARE is a method to determine the hazard potency of VOC and the hazard of a product containing VOC which can be communicated to the user as the AWARE code. The use of the AWARE code on products gives users the possibility to compare products and choose safer products. The AWARE method allows product developers to estimate and reduce the hazard potency of their products. Together, this is expected to result in a reduction in the use of and exposure to hazardous substances by workers.

The AWARE method was developed by SZW in co-operation with industry based on existing methods. The AWARE method and its scientific basis are described in the report 'The AWARE code' (Krop et al., 2007). A peer review of the AWARE method was regarded necessary before further steps towards the introduction of AWARE were taken. Therefore, several aspects of AWARE and their scientific basis as described in that report were reviewed in this report.

The use of two AWARE codes results in a problem in the interpretation of the AWARE codes that is not covered in the AWARE report. Namely, what is the safest product if a product has a higher $AWARE_1$ but a lower $AWARE_2$ than another product. Also, as the AWARE codes are only relative values, it cannot be excluded that products which are already safe are replaced by products that are also safe but have lower AWARE codes.

The approach used for $AWARE_1$ is based on a standardized risk or hazard potency determined from the ratio between the OEL and the standardized exposure. The standardized exposure is based on 1 litre of product in a space of $1m^3$. Therefore, this approach does not take into account other factors which are important for the actual exposure and risk such as the amount of product required, exposure duration and frequency and risk management measures. As these factors may also vary between comparable products it can be concluded that the standardized exposure is not always a correct estimate to compare the exposure. The method used in AWARE for the estimation of the standardized exposure has a better physical-chemical basis than other screening tools for VOCs. Nevertheless, it is of the utmost importance that the developers of the $AWARE_1$ exposure model elucidate their unclear assumptions. We encourage the development of a tool with a correct definition of the evaporation factor but we also conclude that more research on the uncertainty of the assumptions is necessary.

The OEL part of the $AWARE_1$ is based on the available OEL for that substance or a default OEL in the absence of an acceptable OEL. The AWARE report provides a priority list for the choice of the best OEL and a banding method for estimation of the default OEL based on the classification for substances without an OEL. The AWARE tool provides a list of available OELs. The approach as taken in the AWARE-report is similar to that offered in the SER-Leidraad. However, as to the actual priority in sources for individual OELs there are substantial differences. Accordingly adherence to the selection criteria from the Leidraad would frequently lead to different OELs compared to the data base of values as incorporated in AWARE. Moreover the latter data base contains all Dutch OELs which have been withdrawn on 01-01-2007 (n=800). Also the default approach as recommended in the AWARE-report differs from that recommended in the Leidraad. We recommend that OELs as included in AWARE be updated using the criteria from the Leidraad in order to achieve a data base that provides the user with the best available values from a scientific point of view. Where default values are needed the Kick-off approach should be used (in agreement with the Leidraad). For transparancy and consistency all values should be properly referenced. In the near future, the DNELs available from REACH could be used as alternatives for some OELs and especially for substances without an OEL because hazard banding

based on classification is not very accurate and only takes into account the known hazards of the substance. The use of DNELs and the increase in available toxicological data from REACH is expected to substantially increase the accuracy of the OEL for the $AWARE_1$.

The $AWARE_2$ accounts for the hazards that are not included in the $AWARE_1$, hazards like irritation, allergenicity, mutagenicity, reproductive toxic effects and carcinogenicity especially for non-inhalatory exposure. The $AWARE_2$ code system is based on the classification of the preparation. The R-phrases are assigned an $AWARE_2$ code number according to a table and the "highest" risk phrase determines the $AWARE_2$ code. Hazard banding based on classification is not very accurate and only takes into account the known hazards of the substance. This may therefore lead to the substitution of hazardous products with products of unknown hazardous properties. The new CLP legislation on classification and labelling of substances and mixtures can be used for the $AWARE_2$ in the same way as the current legislation but has the same limitations. The DNELs which will be available from REACH for most substances will be a much better indication of the hazard potency of most substances because it is a quantitative estimate based on all available toxicological data. Also the available data will increase under REACH. Development of an $AWARE_2$ based on the DNEL is therefore recommended.

Based on the current peer review, it can be concluded that the AWARE method provides an indication of the standardized risk and hazard of products based on a limited method description and justification. The precision of the AWARE method could be increased by the use of the DNEL values. It could be recommended to develop an AWARE method in which all hazard estimates based on classification banding are replaced with DNELs where available. This includes the $AWARE_2$ and a part of the OELs for $AWARE_1$. The method description and justification could be improved based on the recommendations in this report. Further, it could be recommended to validate the improved AWARE method by comparing the AWARE results with a full risk assessment for a number of products and their substitute products. This would provide an indication of the discriminatory power of AWARE.

Comparison of AWARE with more or less similar tools shows that there are only a limited number of comparable tools and that AWARE has added value over the comparable system, specifically for the exposure part. However, other tools have added value in other areas such as an advice on safe handling.

REACH has the same goal as AWARE, namely the safe use of substances. Both systems provide hazard and safety information to the user of the final product. The AWARE system provides information on the relative safety of the product allowing easy comparison to similar products whereas REACH provides information on the risk management measures required for safety. The information provided under REACH allows a comparison of the operational conditions and required risk management measures for a certain use between products and thus an indirect comparison of the relative hazards of similar products. But as long as the user adheres to the operational conditions and risk management measures the use of all products should be safe. Therefore, it seems that AWARE has little added value under REACH.

Given the gradual phase-in of existing substances in REACH, it will take years before the essential information becomes available for all substances. The methodology of AWARE and the experience gained with it, might therefore be useful in the meantime. However, further development of AWARE will also require considerable time. Introduction of AWARE in the Netherlands but also in a European system will take time and will require action from the same industry working on the requirements of REACH. Also, the new toxicological data becoming available under REACH may change the AWARE code and the conclusions based on it.

Overall, it is concluded that AWARE is a useful but imprecise tool to reduce the risks of VOC containing products. The precision and the scientific substantiation can be increased based on the recommendations proposed in this report. However, in the long run AWARE has little added value once REACH has been implemented.

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Appendix 1

An alternative derivation of the AWARE$_1$

Assumption 1: the ideal gas law holds (which is generally valid at standard room temperature and pressure).
From this assumption one can derive that the vapour/gas concentration of a substance with pressure p [Pa] in a volume V [m^3] at temperature T [K] and molecular weight M [g/mol] is given by:

$$C = \frac{nM}{V} = \frac{pM}{RT} \ [\mathrm{g/m^3}] \tag{A.1}$$

Assumption 2: the volume V is considered to be "small enough", such that the composition of the product in equilibrium with the surrounding volume is not changed during the process of reaching equilibrium. Notably, in this sense, none of the liquid constituents of the product is exhausted.
The relation between the concentration of a constituent in the liquid fraction of the product and its vapour pressure in air is then given by

$$p = \gamma y^L p^*(T) \tag{A.2}$$

where γ is the activity [-], y^L the molar fraction [-] and p^* the vapour pressure [Pa] of the constituent. Note that the vapour pressure is a function of the ambient temperature.

Digression about the activity (see for example. Atkins, Physical Chemistry):
For ideal mixtures of liquids, such as benzene and toluene, Raoult's law states $\gamma = 1$. Generally however, Raoult's law is not valid and the activity is a complicated function of the mixture composition. Nevertheless, most often in the limit of the molar fraction of one constituent $y^L \to 1$, its activity $\gamma \to 1$. Henry found for the other constituents for which the molar fractions are in the limit $y^L \to 0$, that $\gamma \to H \neq 1$. For mixtures that do not fulfil these limits on molar fractions both approaches can be quite wrong.
End of digression.

Let $W_p = d_p V_p$ the weight [kg] of the product (a can of paint, say), where d_p is the products density [kg/L] and V_p the products volume [L]. If ω_i^L is the weight fraction [g/kg] of the products constituent i in the liquid phase, than $w_i^L = \omega_i^L W_p$ is the weight [g] of constituent i in the product. So, $n_i^L = w_i^L / M_i$ is the number of moles and the molar fraction of constituent i in the liquid is

$$y_i^L = \frac{n_i^L}{\sum_j n_j^L} = \frac{w_i^L / M_i}{\sum_j w_j^L / M_j} = \frac{\omega_i^L / M_i}{\sum_j \omega_j^L / M_j} \tag{A.3}$$

Thus, the equilibrium concentration in ambient air of liquid constituent i is:

$$C_i = \frac{\gamma_i y_i^L p_i^*(T) M_i}{RT} = \frac{\omega_i^L}{\sum_j \omega_j^L / M_j}[\text{g/mol}] \cdot \frac{\gamma_i p_i^*(T)}{RT}[\text{mol/m}^3] \qquad \text{(A.4)}$$

Note that the first term at the right side is completely determined by the products liquid composition and the second term by the physical property of constituent i. Note the harmonic mean of the molecular weight of the liquid fraction of the product is given by

$$\frac{1}{M_{harm}^L} = \sum_j \frac{\omega_j^L / M_j}{\sum_k \omega_k^L} \quad \Rightarrow \quad \frac{1}{\sum_j \omega_j^L / M_j} = \frac{M_{harm}^L}{\sum_k \omega_k^L} \qquad \text{(A.5)}$$

So, alternatively, equation (A.4) can be rewritten as

$$C_i = \frac{\omega_i^L M_{harm}^L}{\sum_j \omega_j^L} \frac{\gamma_i p_i^*(T)}{RT}[\text{g/m}^3] \qquad \text{(A.6)}$$

In practice, the Occupational Exposure Limit is expressed in units of [mg/m^3], so taking $[\text{OEL}]_i = 10^3 \cdot C_i^{OEL}\ [\text{mg/m}^3]$, it follows that

$$\begin{aligned} \frac{C_i}{C_i^{OEL}} &= \frac{10^3\ [\text{mg/g}]}{[\text{OEL}]_i\ [\text{mg/m}^3]} \cdot \frac{\omega_i^L}{\sum_j \omega_j^L / M_j}[\text{g/mol}] \cdot \frac{\gamma_i p_i^*(T)}{RT}[\text{mol/m}^3] \\ &= \frac{10^3 \cdot}{[\text{OEL}]_i} \frac{\omega_i^L M_{harm}^L}{\sum_j \omega_j^L} \frac{\gamma_i p_i^*(T)}{RT} \end{aligned} \qquad \text{(A.7)}$$

Note that the first term at the right side of the first line and in the second line is purely of toxicological risk concern. Multiplying the numerator and denominator at the right side of the first line and in the second line by W_p and realising that the total number of moles in the liquid fraction is $n_{tot}^L = \sum_j w_j / M_j$, equation (A.7) can also be written as

$$\frac{C_i}{C_i^{OEL}} = \frac{10^3 \cdot}{[\text{OEL}]_i} \frac{w_i^L}{n_{tot}^L} \frac{\gamma_i p_i^*(T)}{RT} \qquad \text{(A.8)}$$

If one expresses the composition of the liquid fraction in terms of *c* % of constituent weight [kg] per weight of product [kg], then $w_i^L = 10 c_i^L W_p = 10 c_i^L d_p V_p$ one obtains

$$\frac{C_i}{C_i^{OEL}} = \frac{10^4 \cdot}{[\mathrm{OEL}]_i} \frac{c_i^L d_p V_p}{n_{tot}^L} \frac{\gamma_i p_i^*(T)}{RT} \tag{A.9}$$

which much resembles equation (2.14) of the 'AWARE report', but for the product volume V_p which is assumed have the standard value of 1 [L] and for the activity coeffiecient γ which has
Assumption 3: the standard value $\gamma = 1$. This value is only replaced by Henry's coefficient for soluble gases.

Equation (A.9) is equivalent to

$$\frac{C_i}{C_i^{OEL}} = \frac{10^4 \cdot c_i^L d_p}{[\mathrm{OEL}]_i} \frac{V_p}{V} \frac{\gamma_i p_i^*(T)}{p_{virtual}} \tag{A.10}$$

where $p_{virtual} = n_{tot}^L RT / V$ is the pressure that is exercised at the ambient temperature by n_{tot}^L moles in the volume *V*. The first term has unit [m^3/L], and the second has unit [L/m^3].

Assumption 4: the standard value of $V_p / (p_{virtual} V) = 1/30000$

Together wit assumption 3, one obtains

$$\frac{C_i}{C_i^{OEL}} = \frac{c_i^L d_p}{[\mathrm{OEL}]_i} \frac{p_i^*(T)}{3} \tag{A.11}$$

which is equation (2.18) at page 9 of (Krop et al., 2007).
The assumptions 2, 3 and 4 are very powerful!

Our reasoning would be that the virtual pressure $n_i^L RT / V$ of constituent i can in reality never exceed the vapour pressure p_i^* of that constituent when existing as a pure liquid (not as constituent of a mix). So, $C_i = M_i \max(p_i, p_i^*(T))$ and

$$\frac{C_i}{C_i^{OEL}} = \frac{10^3}{[\mathrm{OEL}]_i} \max(10 c_i^L d_p \frac{V_p}{V}, \frac{M_i p_i^*(T)}{RT}) \tag{A.12}$$

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Appendix 2

Long list of potentially relevant tools for comparison with AWARE and evaluation of relevance at first glance

Table 7. Long list of tools that may have partly similar functions as AWARE and first assessment of their relevance

Tool	General purpose of the tool	Relevance	Remarks
Knowledge system rubber industry	On-line system to assist employers in the rubber industry to decrease the risks of chemicals in their industry	Possibly relevant	• Hazard assessed through OELs or indicative limits from hazard banding • Exposure assessed through measured data or EASE modelling • Risk assessed by comparison of exposure and hazard • Contains a database of information on rubber chemicals
Buying guide for personal protection	Guide to assist in the selection of personal protection.	Not relevant	• Too general, refers to other documents
COSHH Essentials	Tool provides advice on controlling the use of chemicals for a range of common tasks	Relevant	• Hazard banding system • Exposure banding system • Choice of control regime • General and specific control sheets
Classification system for release agents (SUMOVERA)	Assistance in choosing release agents based on hazards for environment and humans, including transport safety	Possibly relevant	• Mostly based on environmental risks • Only relevant factors for humans are R-phrases and flash point
Control guide	Digital tool for fitting control measures to the specific exposure situation	Not relevant	• Only relates to control measures, effectiveness and costs
Product Stewardship Management Tool	Tool to assist companies in the product stewardship	Not relevant	• Tool for administrating activities in product stewardship and regulatory affairs (e.g. REACH)
UIC DT63	Provision of advice to SMEs on safe handling of chemicals	Possibly relevant	• Provides risk management advice • Focusses on ventilation

Tool	General purpose of the tool	Relevance	Remarks
UIC DT80	Provision of risk management advice for workplace use of chemicals	Possibly relevant	• Combination of a very general screening tool and a somewhat more extensive screening tool • Provides general advice on risk management measures • Replaces UIC DT63
Giscodes + product codes (Wingis online)	On-line system providing advice on risks and handling of chemical building products.	Relevant	• Product code system, based on composition of product (including percentage of types of substances) and hazard • In the system Wingis online for each product a description and a pictorial view (green to red slide) of inhalation, dermal and physico-chemical 'hazards' is provided separately for manual work and spray application. Because of this separation it is highly probable that some aspects of exposure are included in this view. • Part of the GISBAU system that also includes a database of protective gloves
ECETOC TRA	Screening risk assessment of substances, specifically in regulatory assessments	Possibly relevant	• Hazard banding systeem • Exposure model
Classification system for shoe repair products	Assist in choice of shoe repair products based on relative emission potential and hazard	Relevant	• Uses the OAR (predecessor of AWARE) code for inhalation and $AWARE_2$ for dermal classification • Because of similarities between OAR and $AWARE_1$ this system is not further evaluated.
ILO Chemical Control Toolkit	Tool for SMEs with the aim to provide simple and practical means to prevent/reduce risks of chemicals	Relevant	• Hazard banding system • Exposure banding system • Guidance for safe handling • General and task-specific control guidance sheet(s) • Based on COSHH essentials
CONSEXPO	ConsExpo is a set of coherent, general models that enables the estimation and assessment of the exposure to substances from consumer products and their uptake by humans.	Not relevant	• Only consumer exposure modelling

Tool	General purpose of the tool	Relevance	Remarks
Branchecodes	Tools to help branches in a standardised way to reduce risks in their companies.	Not relevant	• Only information, no system
Canadian approach on categorization of substances	Prioritizing substances for further regulatory assessment	Possibly relevant	• Very rough prioritizing system based on rather general information • Considered too general for further evaluation
PISA	Tool to assist in generation of information sheets on handling and use of chemicals in building materials and products	Possibly relevant	• Register with toxic substances/products • Generation of information sheets for employers/employees • Manual comparison of information sheets allows for some ranking of products • Identifies precautionary measures for selected products • Identifies first aid measures • Advice on storage and disposal of products
Decision model for replacement of products with VOCs	Assist in choice of alternative products in the furniture industry	Not relevant	• Flow diagram showing possibilities for replacement, based on product quality and performance and general product characteristics (amongst others. VOC content)
DOHSBase	Tool to assist in ranking of chemical substances according to calculated risk	Possibly relevant	• Hazards score (hazard band) (TOX) • Maximal concentration in air score (TIX) • Risk assessment score (RAS) = TOX * TIX

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