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ECETOC TRA v3 Worker module: Comparison of measured and modelled shortterm inhalation and dermal exposure; Changes to tool settings

Technical Report No. 141

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

ECETOC TRA v3 Worker module: Comparison of measured and modelled short-term inhalation and dermal exposure; Changes to tool settings

Technical Report No. 141

Brussels, September 2023

ISSN-2079-1526-141 (online)

ECETOC Technical Report No. 141

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SUMMARY

The ECETOC Targeted Risk Assessment (TRA) tool has been widely used by REACH¹ registrant companies in Europe to create screening level exposure assessments for REACH dossiers of chemical substances since 2010. The tool module dealing with occupational exposure ('TRA Worker') provides base estimates for inhalation exposures to vapours released by liquid substances and to dust released by solid substances and for dermal exposures to all substances regardless of physical state, for a series of standardised worker activities, called Process Categories (PROCs). The base estimates are subdivided across broad categories of vapour pressure and dustiness and can be adjusted for a limited set of operational conditions and risk management measures, such as ventilation in the work environment, concentration of the substance of interest in a product, shortened duration of exposure, and use of personal protective equipment.

Because the performance of the TRA Worker module has been studied and questioned by several external research groups since 2010, an ECETOC Task Force (TF) reviewed these published performance studies which relied mainly on exposure measurement datasets and associated descriptions of operational conditions and risk management measures in actual workplaces, which were compared with TRA-generated estimates. If necessary, the TF retrieved additional information to examine the researchers' application of the TRA in detail. The review analysis focussed on measurement reports with more substantive datasets as these provided more certainty about the existing exposure levels and allowed to create a high-quality curated database for future studies.

The analysis resulted in useful insights regarding the performance of the TRA Worker module but revealed also some recurring errors in the application of the TRA. The methodology of analysis and the results with focus on full-shift inhalation exposure were consequently reported in the ECETOC Technical Report No. 140 (ECETOC, 2022) and a peer-reviewed scientific publication (Savic et al., 2023). The present report contains similar analyses for subsets of published performance studies with information on short-term inhalation exposure (typically 15 minutes) and dermal exposure. Using these datasets, additional databases for short-term and for dermal data were constructed consisting of datasets of six or more measurements from workplace assessments with sufficiently detailed information on operating conditions and risk management measures to derive TRA short-term inhalation or dermal exposure estimates, respectively.

The TF found that only limited data on short-term inhalation and dermal exposure are available for analysis as compared with the data available on full-shift inhalation exposure. An overall assessment of the tool's performance on estimating exposure for all potential existing workplace situations is therefore not possible. However, together with the results from the analysis of the full-shift inhalation reported in the previous report (Technical Report (TR) 140) and the scientific publication, the data from the current analysis provide a sufficiently solid base for an update of the TRA tool including adjustments of selected base estimates and efficiencies of the modifying factor for local exhaust ventilation (LEV). The changes concern PROCs 7, 8a, 8b,

¹ Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation, (EC) No 1272/2008

10, 17 and 18. The revised 'look-up tables', that form the basis of the updated TRA for workers (new version 3.2), are included in the present report.

The analyses completed in this part of the study indicated overestimation by the TRA of actual measured levels of workers in 87% of short-term inhalation exposure scenarios and 82% in dermal exposure scenarios. The changes in the updated tool settings have further increased these to 92% and 87%, respectively. Overall, the performed analysis and settings update confirm that the TRA is a suitable screening tool for occupational exposure estimation in the preparation of REACH dossiers for chemical substances.

1. INTRODUCTION

ECETOC developed the Targeted Risk Assessment tool (ECETOC TRA) to support companies in preparing REACH registration dossiers, as it generates screening level estimates of human and environmental exposures to classified chemical substances. The tool has been very widely used for that purpose since 2010. Because of its relative ease of use and transparent approach, the module dealing with occupational worker estimation ('TRA Worker') is also finding application in workflows to meet regulatory obligations under worker health protection legislation around the world.

The TRA is intended as a screening tool that produces moderate overestimates of human exposure to chemicals under normal circumstances of intended use or, where conditions of use are variable across a market segment, reasonable worst-case estimates. If in such a risk assessment workflow at the screening level, the estimated exposure is judged to be not adequately controlled, then the assessor is typically expected to resort to higher, more complex exposure estimation tools or measured datasets. A number of research groups have undertaken validation studies of the TRA tool estimates for worker exposures and reported these in the literature. Typically, these studies have utilised measured workplace exposure data along with contextual information on the tasks and workplace settings and then constructed corresponding TRA estimates for comparison. While a wide variety of results have been published, the most prominent study is the ETEAM study coordinated by the German Federal Institute for Occupational Safety and Health (BAuA), where several exposure estimations tools were compared against 2098 exposure measurements (Tischer et al., 2017). Additionally, the Cefic Long-Range Research Initiative (LRI) funded research projects B16 and B20 which addressed aspects of the TRA (Marquart et al., 2017; Franken et al., 2020).

As for all models, the outcome of ECETOC TRA is highly dependent on the selected input parameters by the assessor based on experience and knowledge of the tool as well as the degree of information on the scenario to assess. At its simplest, the TRA Worker module covers 26 different conditions of workplace use (termed PROCs) of chemicals and enables exposure estimates to be obtained for a range of different types of volatile liquids and solids. In total 261 estimates describe the 26 PROCs contained in the TRA Worker module for full-shift inhalation exposure. Additionally, the tool can provide estimates for short-term inhalation exposure (typically 15 minutes) and dermal exposure. The model was derived from the exposure estimates as the upper end of interquartile bands originally described in the UK Health and Safety Executive (HSE) Estimation and Assessment of Substance Exposure (EASE) model, and hence the 75th percentile of the exposure distribution for a use group, which consequently provides a historical link to the regulatory decisions made in previous EU chemicals regimes. The TRA Worker module continues to use the 75th percentile but additionally describes the exposure experiences that might be expected to arise when workers (and their employers) follow the basic conditions of exposure control implied by EU Directives 89/391/EEC (1989, safety and health of workers) and 98/24/EC (1998, chemical Agents).

As the tool owner, ECETOC is committed to maintain a watching brief on such validation studies and to review these research projects periodically, particularly if such research suggests deviations from expected performance of the TRA. If found necessary, tool users will be informed, and guidance will be adjusted.

As a series of validation study projects have been reported in the period of 2010 - 2020, ECETOC assembled an expert Task Force (TF) to review the presented results and conclusions, and propose any adjustments to tool settings or improvements to user guidance.

Consequently, the TF reviewed the different validation studies and projects in detail, considering the quality and quantity of data used, the coverage of TRA Worker module's applicability domain, and the validity of the published research. An overview of the available material of the projects as well as an indication of the adopted review and analysis approach was already published (Urbanus et al., 2020).

TR 140 provides a detailed review of studies on the inhalation exposure estimation performance of the TRA Worker module by external research groups since 2010 (ECETOC, 2022). The review focussed on measurement reports with more substantive datasets (i.e., six or more datapoints in line with current recommended practice for compliance testing with occupational exposure limits) as these provided more certainty about the existing exposure levels and also presented the possibility to create a high-quality, pooled database for future studies. Using a selection of the higher quality datasets in the published materials, representing approximately two thirds of the original material, a curated database was constructed consisting of datasets of six measurements or more from workplace assessments with sufficiently detailed operating conditions and risk management measures to derive a TRA estimate and for which the 75th percentile was calculated from the measurements for comparison. The results of the performance assessment of the TRA Worker module for full-shift inhalation exposure based on comparison with the curated database have been reported separately in a published paper available under Open Access (Savic et al., 2023).

A subset of the reviewed studies also contained measurement reports with information on short-term inhalation exposure (typically 15 minutes). Using these datasets, a second database was constructed consisting of datasets of six measurements or more from workplace assessments with sufficiently detailed operating conditions and risk management measures to derive a TRA short-term inhalation estimate, typically required for chemicals with a Derived No Effect Level (DNEL) for acute effects.

Following an identical approach as for full-shift inhalation exposure, the TRA TF also retrieved and evaluated studies containing information that can be used to evaluate the performance of the TRA Worker module for dermal exposure. Only two studies have been identified, one in which the dermal exposure model of the TRA Worker module has been validated (Cefic LRI B16 study, reported in Marquart et al., 2017) and one in which five typical worker activities (represented by PROC's) have been simulated, while measuring dermal exposure (Cefic LRI B20 study, reported in Franken et al., 2020). As with the full-shift inhalation exposure study, only datasets containing six measurements or more were reviewed. The selected datasets have been used to create a third curated database consisting of datasets from workplace assessments with sufficiently detailed operating conditions and risk management measures to derive a TRA dermal estimate.

Both for short-term inhalation and dermal exposure the derived TRA estimates have been used to compare with the 75th percentiles calculated from the measurement data.

This report provides the results of the review of the performance assessment for short-term inhalation and dermal exposure. Based on the results of the full-shift inhalation assessment reported in the publication by Savic et al. (2023) (as well as TR 140 (ECETOC, 2022) and the present report), adjustments are defined to some

of the base estimates and the efficiency of the modifying factor for LEV which will be implemented in the next version of the TRA tool.

The curated databases used in this work are available on the ECETOC webpage alongside this TR and can be accessed from the links below:

- TRA v3 dermal supplementary data
- TRA v3 short-term inhalation supplementary data
- TRA v3 long-term inhalation supplementary data

2. METHODOLOGY

2.1 Systematic review of short-term inhalation exposure studies

The systematic review of the short-term inhalation exposure datasets has been performed simultaneously with the analysis of the 8-hour time weighted average (TWA) inhalation exposure datasets, as described in detail in the ECETOC TR 140 (ECETOC, 2022). All dataset information was verified by at least two members of the TF. Where the reviewers had reason to disagree with the TRA Worker module inputs by the original authors of the validation studies, contact was sought with them if the rationale remained unclear from the documented workplace investigations to understand the basis for the differences. The feedback was then discussed in the TF until consensus was achieved, and where justified the original inputs were corrected and the TRA short-term inhalation estimate was recalculated. The review of the input information and the justification for the correction was documented in the curated databases.

2.2 Systematic review of dermal exposure studies

The systematic review of the two dermal exposure studies has been performed in a similar way as the review of the inhalation exposure studies (ECETOC, 2022). All measurement data available from the validation studies were verified and assessed using state-of-the-art approaches from the field of occupational hygiene for the characterisation of an exposure profile of a similar exposure group (SEG) in a particular location or situation. Consequently, reported situation/tasks covering an individual SEG with less than six individual measurements were not regarded as valid for a detailed analysis as a lower number of measurements would not reflect the existing workplace exposure with sufficient confidence.

In the Cefic LRI B16 study (Marquart et al., 2017) more than 100 datasets from 38 data sources were derived, of which 76 datasets contained more than six measurements. One dataset was excluded as the TRA does not provide a dermal estimate for the worker activity under review. As limited resources were available, the information on operating conditions and risk management measures to derive a TRA dermal estimate has only been reviewed for datasets with a ratio P75/TRA higher than 0.05 (37 datasets). For these datasets the TF attempted to retrieve and review the original publications. For two datasets no original publication was available. All information on the dermal exposure measurements was verified by at least two members of the TF. Where the reviewers had reason to disagree with the TRA Worker module inputs by the original authors of the validation studies, this has been discussed in the TF until consensus was achieved, and where justified the original inputs were corrected and the TRA dermal estimate was recalculated. The review of the input information and the justification for the correction is documented in Appendix A.

The Cefic LRI B16 study identified a significant number of datasets for solid substances used in a liquid matrix (e.g., solvent). Although the TRA does not cover solids in liquids, it was decided to include these datasets as a separate category solids-in-liquids (Marquart et al., 2017). For these datasets the substance was always considered to be a liquid with negligible vapour pressure, in line with the approach for dermal exposure assessment for periods shorter than 8 hours as described in ECETOC TR 114 (ECETOC, 2012; paragraph 2.3.3).

The Cefic LRI B20 study (Franken et al., 2020) contains seven datasets with more than six measurements. All datasets were reviewed, following an identical process as described above. No changes have been made to the original inputs.

The quality of the data in all dermal exposure datasets was systematically evaluated using the same rating criteria as for the inhalation exposure datasets (ECETOC, 2022), based on a rating system developed by Franken et al. (2020).

2.3 Performance assessment for short-term inhalation and dermal exposure

Both for short-term inhalation and dermal exposure the derived TRA estimates for each exposure scenario (ES) have been used to compare with the 75th percentile calculated from the measurement data. Because of the intended conservative nature of the TRA, the required outcome had to be an overestimate of the tool output compared to the measurement result taken for comparison. The difference between tool output and measurement result is termed DeltaTRA. In addition, the totality of available data was examined in regression analysis and by calculating a Mean Absolute Error.

For the short-term inhalation data, the 75th percentile was calculated either directly from the individual measurement results, if available, or from the geometric mean (GM) and standard deviation (GSD). Equation 1 was applied to calculate the 75th percentile for the measured exposure, using GM and GSD and a z-score of 0.674. Log-normal distribution was assumed.

Equation 1: $P75 = GM \cdot GSD^Z$

For the dermal inhalation data, the 75th percentile as provided by the original authors of the validation studies has been used, as insufficient information for recalculation was available.

All statistical calculations and the visualisation of the obtained results were conducted in Excel.

Regression. A regression model was established to estimate intercept (a), slope (b) and R²-score between the measured and the modelled (i.e., TRA) estimates. Since occupational exposure usually follows a lognormal distribution, the log-transformation was applied on the 75th percentile calculated from the measurements (P75) and the modelled exposure estimate. These data points were plotted to illustrate how they follow the established regression line. In an ideal situation, the regression line should go to zero and have a slope of 1, meaning that the model calculates the same exposure value as given by the measurement data. R²-score, or the coefficient of determination, was evaluated to show how much variance in the measurements the TRA could explain.

Delta_{TRA}. This parameter was calculated to aid visualisation of local trends between the measured and modelled exposure. As shown in Equation 2, a residual (termed 'delta_{TRA}' in the publication of Savic et al., 2023) is calculated as a difference between the logs of the modelled (TRA) and its corresponding measured value (P75). While positive delta_{TRA} values indicate overestimation, negative values indicate an underestimation of the measurements by the model.

Equation 2: $delta_{TRA} = logTRA - logP75$

Mean Absolute Error (MAE). The mean of the absolute differences between the modelled and measured exposure in Equation 3 defines another performance measure called Mean Absolute Error (Walther and Moores, 2005). While residuals are calculated for all data points, MAE is calculated as a single value. This parameter shows how far, on average, the modelled estimates are away from the measured values for a dataset with 'n' ESs.

Equation 3: $MAE = (1/n) \sum_{i=0}^{n} |logTRA - logP75|$

If, for example, MAE equals 1.0, this would mean that the modelled and measured values differ on average by one order of magnitude, thus a factor of ten since the difference is on the log scale.

3. FINDINGS

3.1 Overview of short-term inhalation and dermal exposure databases

3.1.1 Short-term inhalation exposure database

The short-term inhalation database contains 41 scenarios from 8 studies, covering 428 measurements. Table 1 provides an overview of the datasets in the short-term inhalation database. The majority of datasets concern liquid exposure scenarios. Three datasets are considered not to be valid for TRA comparison due to the low data quality of the exposure survey. Descriptions of the data sources were included in the Appendices of TR 140 (ECETOC, 2022).

Scenarios	# scenarios	# measurements	
Liquids	36	356	
Solids	2	43	
Not valid	3	29	
Main sources	# scenarios	# measurements	
Angelini et al., 2016	14	105	
Lee et al., 2019	8	74	
Concawe, 2018	7	100	
Tischer et al., 2017	6	83	

Table 1: Overview of datasets in the short-term inhalation database

Figure 1 shows the coverage of PROCs by the datasets. For most PROCs there are no data available. Where there are data available, the number of datasets per PROC is limited, except for PROC8b.



Figure 1: Number of datasets per PROC in the short-term inhalation exposure database

3.1.2 Dermal exposure database

The dermal database contains 83 scenarios from two studies, covering 1733 measurements. These measurements had been done using a variety of methods, such as skin wiping and sample gloves. Note that the datasets in the LRI B16 study (Marquart et al., 2017) are retrieved from 32 original studies. Table 2 provides an overview of the datasets in the dermal database. The datasets are relatively evenly spread across liquid, solids in liquid and solid exposure scenarios. One dataset is considered not to be valid for TRA comparison as a TRA estimate is not available for this scenario.

Scenarios	# scenarios	# measurements
Liquids	21	881
Solids in liquids	36	554
Solids	25	284
Not valid	1	14

Sources	# scenarios	# measurements
Studies in Cefic LRI B16 (Marquart et al., 2017)	76	1663
Cefic LRI B20 project, (Franken et al., 2020)	7	70

Figure 2 shows the coverage of PROCs by the datasets. For approximately half of the 26 PROCs, data are available. However, for most PROCs the number of datasets per PROC is limited. Exceptions are PROC10, PROC11 and PROC8a (each with more than 10% of the total datasets).



Figure 2: Number of datasets per PROC in the dermal exposure database

3.2 Correction of input parameters

3.2.1 Correction of input parameters for short-term inhalation exposure

All TRA Worker module input parameters coded by the original authors (i.e., PROC, type of setting (industrial versus professional), general and local exhaust ventilation (LEV), fugacity, duration, concentration, respiratory protection equipment) were reviewed. For a number of the datasets the reviewers disagreed with the input parameter selection by the original authors of the validation studies. Each identified disagreement was discussed in the TF until consensus was achieved and, where justified, the original coding was corrected. The review of the input information and the justification for the correction is documented in ECETOC TR 140 – Appendix A (ECETOC, 2022). Table 3 provides the results of the correction of input parameters. In the majority of cases, the corrections resulted in increased TRA exposure estimates.

Table 3: Codina	i correction i	in the short-ter	m inhalation e	xposure database
				nposure aatabase

Parameter	Corrected (%)
PROC	16
Room ventilation status	39
Local exhaust ventilation (LEV)	37
Substance fugacity	11
Respiratory protection equipment (RPE)	13

For general ventilation and LEV the percentage of coding corrections was high (39% and 37%, respectively). LEV was coded incorrectly in a significant number of datasets from the same facility and for the same substance and activity, while the description of the type of LEV used suggested that the effectiveness would be significantly lower than the 95% as assigned to this activity (PROC) in the TRA Worker module. Therefore, it was decided to change the coding to 'no' for LEV and to 'enhanced ventilation' instead of 'no ventilation'.

3.2.2 Correction of input parameters for dermal exposure

As for the datasets in the inhalation exposure databases also all relevant TRA Worker module input parameters coded by the original authors (i.e., PROC, application for local exhaust ventilation for dermal, fugacity, duration, concentration, dermal protection equipment) were reviewed. Where the reviewers had reason to disagree with the inputs by the original authors, this has been discussed in the TF until consensus was achieved, and where justified the original inputs were corrected. The review of the input information and the justification for the correction is documented in Appendix A. Table 4 gives an overview of the coding corrections on the dermal datasets. In the majority of cases, the corrections resulted in increased TRA exposure estimates.

Table 4: Coding correction in the dermal exposure database

Parameter	Corrected (%)
PROC	2
Local exhaust ventilation – dermal	6
Dermal protection equipment	2

Overall, the percentage of coding corrections for dermal exposure was low.

4. **RESULTS OF THE ANALYSIS**

4.1 Results of the analysis for short-term inhalation exposure

The analysis has been performed on both liquid (n=36) and solid (n=2) datasets. Figure 3 illustrates the relationship between the measured (P75 values) and the modelled (TRA values) exposure (including the regression coefficients and R²-score). The slope of the regression line is almost 1.0, while the intercept is negative, indicating that on average the measured data were lower than the modelled estimates. For the majority of datasets, the TRA estimate is higher than the measured P75. For five datasets (13%) the measured P75 is higher than the TRA estimate. The TRA model parameters accounted for approximately 39% of the observed variance in the measurements.



Figure 3: Measured (P75) versus modelled (TRA) short-term inhalation exposure for liquids and solids

Figure 4 shows the delta_{TRA} versus the measured P75. The calculated delta_{TRA} indicated a tendency of the TRA to underestimate exposure at higher exposure levels. The Mean Absolute Error (MAE) is 1.29, indicating that on average the difference between measured and modelled exposure is more than a factor 10.



Figure 4: DeltaTRA versus measured (P75) short-term inhalation exposure for liquids and solids

Figure 5 gives an overview per PROC of the percentage of available datasets where the measured P75 is higher than the TRA estimate. Underestimation is mostly found for PROC10 and PROC13 and to a lesser extent for PROC8b. Note that for the two solid datasets (PROC15 and PROC19) no underestimation occurred.



Figure 5: Percentage of datasets where TRA Worker module is underestimating measured short-term inhalation exposure per PROC.

4.1.1 Effect of input variables on underestimation

Since for short-term inhalation exposure only a limited number of datasets were available (n=38) and the TRA Worker module underestimated the measured P75 exposure only for five datasets, an additional analysis was not conducted on the effect of modifiers such as general ventilation, LEV, concentration and use of respiratory protection.

4.2 Results of the analysis for dermal exposure

Figure 6 illustrates the relationship between the measured (P75 values) and the modelled exposure for the three categories (solids, liquids and solids in liquids) as well as the corresponding regression coefficients and R²-score. The slope of the regression line was close to 1.0, however the intercept is negative, which indicates that on average the measured data were lower than the modelled estimates. For the majority of datasets, the TRA estimate is higher than the measured P75. For 15 out of 82 datasets (18 %) the measured P75 is higher than the TRA estimate.

The TRA model parameters accounted for approximately 35% of the observed variance in the measurements.



Figure 6: Measured (P75) versus modelled (TRA) dermal exposure

Figure 7 also provides the relation between measured and modelled exposure, however now for the three categories separately. For all three categories on average the measured data were lower than the modelled estimates, although for liquids the regression line is nearing the unity line (P75/TRA = 1) at higher exposure levels.



Figure 7: Measured (P75) versus modelled (TRA) dermal exposure per category (solids, liquids and solids in liquids)

Figure 8 shows the delta_{TRA} versus the measured P75. The calculated delta_{TRA} values indicate a tendency of the TRA to underestimate exposure at higher exposure levels. The Mean Absolute Error (MAE) is 1.44, indicating that on average the difference between measured and modelled exposure is approximately a factor 28.



Figure 8: Delta_{TRA} versus measured (P75) dermal exposure

Figure 9 gives an overview of the percentage of datasets where the measured P75 is higher than the TRA estimate per PROC. Underestimation is mostly found for PROC5 and PROC8a and to a lesser extent for PROC7 and PROC13. Note that for PROC17 and PROC24 the underestimation is also high, however for both PROCs only two datasets were available.



Figure 9: Percentage of datasets underestimating measured dermal exposure per PROC

4.2.1 Effect of input variables on underestimation

To investigate the effect of the variables, PROC, concentration of the substance, type of setting (industrial/professional), presence of LEV and use of dermal protective equipment on underestimation, delta_{TRA} were plotted for each variable (Figure 10 and Figure 11).



Figure 10: Delta_{TRA} (dermal exposure) per PROC



Figure 11: Delta_{TRA} (dermal exposure) for type of setting (industrial/professional), concentration of the substance, presence of LEV and use of safety gloves

For the PROCs, in particular PROC8a and PROC24 were more prone to underestimation than the other PROCs. Note, however, that for PROC24 only two datasets were available. With respect to fugacity a significant effect was not found within the volatility bands (most of the datasets are within the low and high volatility bands). For the variable concentration there seems to be some tendency to underestimation at the highest concentration band. Also, for type of setting, presence of LEV and use of dermal protection equipment a tendency to underestimate exists for the parameters industrial setting, no presence of LEV and no use of gloves, respectively.

5. PLANNED CHANGES TO THE TRA WORKER MODULE

5.1 Changes identified based on analysis of long-term inhalation, short-term inhalation and dermal exposure predictions

The analysis of full-shift inhalation predictions reported in TR 140 (ECETOC, 2022) and Savic et al. (2023), pointed towards situations where the TRA did not appear to be sufficiently conservative, but for which adequate datasets are available to suggest changes in the basic look-up tables of the TRA Worker module (look-up tables in the current TRA Worker module (TRA version 3.1) are set out in TR 114 (ECETOC, 2012)). This would concern in particular efficiency of LEV and industrial PROC 10 (medium volatility liquids) predictions. The former aspect is addressed by aligning LEV efficiency across the tool for industrial predictions at a standard of 90% and for professional predictions at 80%, thus removing several higher efficiencies embedded in TRA tool version 3.1, such as for PROC 7 and PROC 8b. The latter aspect is addressed by doubling the base estimate from 50 to 100 ppm. Other scenarios associated with underestimates had insufficient numbers of datasets to justify and introduce meaningful changes.

The short-term inhalation data analysis did not produce any separate suggestions of required changes. However, the dermal data analysis indicated the need to increase the base estimate for PROC 8a in order to produce suitably conservative exposure estimates.

It is noted that for all three databases (full-shift inhalation, short-term inhalation and dermal) the majority of scenarios were overestimated by the TRA, in some cases by several orders of magnitude. However, because the tool is intended to be conservative, rather than accurate, and to provide exposure estimation for individual workplaces, no changes to reduce the degree of overestimation are proposed.

5.2 Changes to maintain/improve internal tool consistency

With the proposed changes described above, several further required changes were identified to keep or improve internal consistency, notably the need to double the base estimate for PROC 10, professional (PROF) - medium volatility liquids, from 100 to 200 ppm to keep the logic of professional exposures at twice the level of industrial (IND) exposures. Also, several removal efficiencies by LEV for dermal exposure prediction were not aligned with those for inhalation exposure predictions.

Table 5 below summarises all planned changes to the ECETOC TRA Worker module.

Change #	Parameter	Change	Rationale
LT-1	LEV for PROC 7	Reduce from	Address some LEV underestimates seen in the database
	(inhalation)	95% to 90%	for this PROC.
			Address overall finding for LEV efficiency.
			Align IND LEV % across the tool (except metal PROCs).
LT-2	PROC 8b, IND,	Reduce from	Align IND LEV % across the tool (except metal PROCs).
	LEV	95% to 90%	Address overall finding for LEV efficiency.
LT-3	PROC 8b, PROF,	Reduce from	Align PROF LEV % across the tool (except metal PROCs).
	LEV	90% to 80%	Address overall finding for LEV efficiency.
LT-4	PROC 10, IND,	Increase from	Excessive underestimation observed in database (44%)
	medium	50 ppm to 100	for PROC10 IND/mv scenarios which is not linked to any
	volatility base	ppm	modifiers.
	estimate		
LT-5	PROC 10, PROF,	Increase from	Maintain internal tool logic following IND change LT-4
	medium	100 ppm to 200	(PROF higher than IND). Improved conservatism.
	volatility base	ppm	
	estimate		
D-1	PROC 8a, base	Increase from	Excessive underestimation observed in database (5 out
	estimate, IND	13.71 to 27.43	of 18 scenarios).
		mg/kg/d	PROC 8a is expected to be higher than PROC 8b.
D-2	PROC 8a, base	Increase from	As above (D-1).
	estimate, PROF	13.71 to 27.43	
		mg/kg/d	
D-3	PROC 8b, IND	Reduce LEV	Align with inhalation LEV.
	with LEV	from 95% to	
		90%	
D-4	PROC 17, PROF	Reduce from	Align with inhalation LEV.
	with LEV	90% to 80%	
D-5	PROC 18, PROF	Reduce from	Align with inhalation LEV.
	with LEV	90% to 80%	
D-6	PROC 7, LEV	Reduce LEV	Align with inhalation LEV.
	effect	from 95% to	
		90%	

Table 5: Summary of planned changes to the ECETOC TRA Worker module

The revised TRA Worker module look-up tables are presented in Appendix B. The changes introduced with the current revision are highlighted in red-bold font.

5.3 Impact of the changes on tool performance

The effects of the planned changes set out in Table 5 were quantified in terms of percentage of underestimated scenarios (before and after the planned tool update), see Table 6 below. Remaining underestimations should be limited for the tool to be still suitably conservative, although exact criteria for being "conservative" have not been widely agreed among exposure scientists or codified in a consensus standard. It must be noted that the percentages in Table 6 are not weighted according to the data availability in the underlying databases. For example, the number of datasets per PROC is not evenly distributed and since the observed tool performance across the PROCs is different, the percentages only represent an approximate indication of the degree of underestimation.

Exposure route/duration	Underestimates before changes (%)	Underestimates after changes (%)	
8h TWA inhalation	19	13	
15 min short-term inhalation	13	8	
8h TWA dermal	18	13	

Table 6: Effects of planned changes on underestimation by the ECETOC TRA Worker module

Figure 12 shows the delta_{TRA} versus the measured (P75) exposure after application of the changes set out in Table 6 for the three databases (8h TWA inhalation exposure, 15min short-term exposure, 8h TWA dermal exposure).



Figure 12: Delta_{TRA} versus measured exposure after changes to the TRA Worker module for the three databases (fullshift inhalation, dermal and short-term inhalation)

For both, inhalation (long-term and short-term) and dermal exposure predictions, the changes lead to less datasets with underestimation (P75/TRA>1; negative delta_{TRA}) at the higher end of the exposure values.

6. TOOL PERFORMANCE FOR REACH SAFETY ASSESSMENT

In a REACH risk assessment, the outcome of the exposure assessment is compared with the Derived No-Effect Level (DNEL) by calculation of the Risk Characterisation Ratio (RCR):

Equation 4: RCR = Exposure / DNEL

When the RCR is less than one, the risk is considered to be acceptable (safe use).

As the ECETOC TRA Worker module has been extensively used for risk assessment under REACH, an attempt has been made to assess the probability of so-called 'false negatives'. A 'false negative' is defined as the situation where the outcome of the risk assessment based on exposure prediction using the TRA Worker module leads to the conclusion that the use is safe (RCR_{TRA estimate} <1; TRA/DNEL <1), while in reality, based on existing measurements, the use is NOT safe (RCR_{P75 measured} \geq 1; P75/DNEL \geq 1).

In all three databases a selection has been made of the datasets where a DNEL for the substance has been derived. For substances without a DNEL an (internationally accepted) Occupational Exposure Limit (OEL) has been used instead, if available. For all cases with a DNEL or OEL available, the respective RCR_{TRA estimate} has been calculated. Where the outcome of the RCR_{TRA estimate} indicated a safe use (TRA/(DNEL or OEL)<1), also the RCR_{P75 measured} was calculated (P75/(DNEL or OEL)). The cases where the RCR_{P75 measured} \geq 1 are the 'false negatives'. The results of this exercise have been summarised in Table 7.

Table 7: Calculation of percentage of 'false negatives' for the three databases for substances with a DNEL or OEL (fullshift inhalation, short-term inhalation and dermal)

	8h TWA inhalation	15min short- term inhalation	8h TWA dermal
# of datasets	129	38	82
# of datasets with DNEL or OEL	129	29	32
# of 'false negatives', i.e. RCR _{TRA estimate} <1 and RCR _{P75 measured} ≥1	3	0	1
Percentage 'false negatives'	3/129 = 2.3 %	0/29 = 0 %	1/32 = 3.1 %

Based on this analysis and the percentage 'false negatives' it can be concluded that the probability of an incorrect decision on safe use when using the ECETOC TRA Worker module in REACH risk assessment is very low.

APPENDIX A: REVIEW OF THE DATA SOURCES AND DATASETS OF THE LRI B16 STUDY (P75/TRA > 0.05)

Reference,				
Scenario & Original	Observations			
P75/TRA values				
B16-66	PROC 17 Ind: OK			
	LEV not applicable: OK			
Metal working	Gloves applicable: the original TRA estimate included the use of gloves and a			
fluids	reduction factor of 10 was applied. However, the reported P75 value of 100.982 mg/kg/d can be expressed as a dermal load of 7.4 mg/cm ² (based on			
PROC17 – Ind	TRA surface area of 960 cm ² ; assuming all measured contamination is located on the hands only). In general, the maximum dermal load for liquids (oils) from			
P75/TRA =36.81	immersion is around 6-10 mg/cm ² , as excess contamination will drop off the skin (Cinalli et al., 1992). Comparing the P75 value and this maximum dermal load indicates that the gloves were not effective in preventing dermal exposure in this survey.			
	 The Task Force has excluded the use of gloves from our TRA estimate 			
	 This change leads to a P75/TRA ratio of 3.68 			
B16-77	PROC 7 Ind: OK			
	• LEV applicable: the original TRA estimate included LEV. However, the survey			
Dry powder spray paint	included 23 measurements, spread over five sites. "The spray paint was applied with electrostatic spray guns inside various designs of ventilated open spray booths, all of which incorporated downward and rearward laminar airflow away			
PROC7 – Ind	from the operator's breathing zone and some of which incorporated water recovery from the back wall. Two factories used conveyorised tunnel enclosures			
P75/TRA = 26.29	with windows to spray through, although one operator was observed to lean inside to spray" "hands and sleeves were inside the conveyorised tunnel enclosure". From the description it is clear that the 'LEV' (in this case conveyorised tunnel) was not effective in preventing hand contamination in at			
	least one of the sites.			
	Gloves not applicable: OK			
	The Task Force has excluded the LEV from our TRA estimate			
	• This change leads to a P75/TRA ratio of 1.31			

Reference, Scenario & Original P75/TRA values	Observations
B16-5	 PROC 5 Prof: OK LEV not applicable: OK
Paint mixing	Gloves not applicable: OKNo changes in TRA estimate for this scenario.
PROC5 Prof	 TNO B16 report suggests that the basic estimate for PROC5 may be too low (for high use rates)
P75/TRA 21.25	
B16-71	 PROC 8a Ind: OK LEV applicable: the original TRA estimate included LEV. However, publication
Manual dumping of powder	 states on page 23: LEV is not an exposure modifier. On page 24 it reads that hands are between LEV and dust emission source. Gloves not applicable: OK
PROC8a Ind	 The Task Force has excluded the LEV from our TRA estimate This change leads to a P75/TRA ratio of 1.72
P75/TRA 17.17	
B16-16	 PROC 24 Ind: OK LEV not applicable: OK
Sand blasting -	Gloves not applicable
Copper	 No changes in TRA estimate for this scenario. TNO B16 report suggests that the basic estimate for PBOC24 may be tee low.
PROC 24 Ind	(for high use rates).
P75/TRA 16.71	
B16-32	 PROC 13 Ind: OK LEV applicable: the original TRA estimate included LEV. However, the
Loading/unloading from electroplating baths	measurement data relates to different kinds of baths including chromic acid, nickel chloride and nickel sulphate. LEV was present only in part of the chromic acid baths – so not in all situations. In addition, LEV is not likely to reduce skin exposure in this scenario as it comes from direct contact with immersed
PROC 13 Ind	objects.Gloves applicable: OK
P75/TRA 16.17	 (Long nitrile gloves were in use). The Task Force has excluded the LEV from our TRA estimate This change leads to a P75/TRA ratio of 1.62

Reference, Scenario & Original P75/TRA values	Observations
B16-36	PROC 15 was originally applied for this dataset.
Constant and the second	Note in this experimental study the quantity handled was between 0.2 and 15 kg. For this particular dataset the quantity was 1 kg. TNO B16 has assigned
scooping, weigning	PROC8a to all other datasets, including the transfer of 0.2 kg. The assignment of
solid product	PROC15 for this dataset is not consistent. The Task Force has applied PROC8a
	instead.
PROC15 Prof	LEV not applicable: OK
	Gloves not applicable: OK
P75/TRA = 11.53	Duration modifier was applied in the original TRA estimate: OK. The Task Fares has undeted the DDOC
	 The Task Force has updated the PROC. This change leads to a P75/TPA ratio of 0.29
B16-69	PROC 21 Ind: The Task Force believes that that PROC 8a Ind (Transfer of
	substance or mixture (charging and discharging) at non-dedicated facilities) is
Transport of	more appropriate to apply for this scenario than PROC 21 (Low energy
powder bags	manipulation and handling of substances bound in/on materials or articles).
	LEV not applicable: OK Claves not applicable: OK
PROC21 Ind	 Gloves not applicable. OK This change leads to a P75/TRA ratio of 1.14
P75/TRA 5 50	
1757 TIA 3.50	
B16-14	PROC 8a Ind
	LEV not applicable: OK
Paint filling (=	Gloves not applicable: OK.
supply of paint by	No changes in TRA estimate for this scenario.
potman)	High use rates reported: 218 kg of paint (120 litres). INO B16 report suggests that basic estimate for PROC8a may be too low (for high use rates)
PROC8a Ind	
P75/TRA = 4.62	

Reference, Scenario & Original P75/TRA values	Observations
B16-93	PROC 8b Ind: OK
Packing area (filling drums with powder) PROC8b Ind P75/TRA 2.93	• LEV applicable: the original TRA estimate included LEV. In our view, LEV is not effective for this scenario: skin exposure comes from direct contact. The publication states "If the drum weight needed to be adjusted, the operator removed excess powder using a hand scoop and placed the surplus material into a storage bin located at the workstation. If any of the drums needed to be topped up, the operator used the scoop to transfer powder from the storage bin to the drum. Each packing station was provided with local exhaust ventilation at the filling points so that any airborne dust generated was
	effectively controlled."
	 Gloves applicable: OK (the publication states: "Glove use was regular, but generally only when carrying out manual handing tasks, e.g. lifting drums onto the conveyors. There was potential for skin contact with contaminated surfaces when touching handrails, driving the forklift truck and operating buttons on control panels.") Our TRA estimate still includes gloves but the Task Force has excluded LEV. This change leads to a P75/TRA ratio of 0.15
B16-87	• Report not available; not reviewed (industry delivered data company A, 2009, as cited by Marquart et al., 2017)
Unloading tank	Duration factor was applied in the original TRA estimate
truck at terminal (gasoline)	• No changes in TRA estimate for this scenario.
PROC 8b Ind	
P75/TRA = 2.09	• DBOC 8a Indi OK
В16-43	 FNOC 8a mu. OK FEV not applicable: OK
Loading of pure	 Gloves not applicable: OK
	 No changes in TRA estimate for this scenario
or mixer	
PROC8a Ind	
P75/TRA = 1.85	

Reference,	
Scenario & Original	Observations
P75/TRA values	
B16-56	PROC 8a Ind: OK
Opening and dumping bag into hopper or mixer	 LEV applicable: the TRA estimate originally included LEV. However, LEV will not be effective for this scenario because of direct hand contact with packaging and material – see also below photographs from publication. Gloves not applicable: OK The Task Force has excluded the LEV from our TRA estimate.
PROC8a Ind	• This change leads to a P75/TRA ratio of 0.08
P75/TRA = 1.59	<image/> <image/> <image/> <image/>
	(b)

Figure 13. Example of direct hand contact with packaging and material. (a) Image on the left: a worker picking up a bag of zinc oxide. (b) Image on the right: a worker emptying a bag of zinc oxide.

B16-59	 PROC 11 Prof: OK LEV not applicable: OK
Spraying and wiping NMP containing solvent for graffiti removal	 Gloves not applicable: OK (hand sampling was by cotton gloves (Radiospares) stretched over the protective gloves as potential samplers.) No changes in TRA estimate for this scenario.
PROC11 Prof	
P75/TRA = 1.47	

Reference, Scenario & Original P75/TRA values	Observations
B16-113	PROC 24 Ind: OK
	LEV not applicable: OK
Steel grinding	Gloves applicable: UK No changes in TRA estimate for this scenario
PROC24 Ind	
P75/TRA = 1.42	
B16-70	PROC 8a Ind: OK
	LEV not applicable: OK
Scooping calcium	Gloves not applicable: OK
carbonate	 No changes in TRA estimate for this scenario.
PROC8a Ind	
P75/TRA 1.32	
B16-20	PROC 10 Prof: OK
Laminating -	LEV not applicable: OK
Styrene	Gloves not applicable: OK
	 Duration modifier was applied in the original TRA estimate, however for 1-4 hrs instead of 15min-1hr
PROC 10 Prot	 This change leads to a P75/TRA ratio of 3.24
P75/TRA = 1.08	
B16-74	PROC 10 Prof: OK
	LEV not applicable: OK
Consumer brush	Gloves not applicable: OK
painting of sheds and fences	No changes in TRA estimate for this scenario.
PROC10 Prof	
P75/TRA = 1.06	

Reference, Scenario & Original P75/TRA values	Observations
B16-12 Spraying of antifouling paint – copper	 PROC 7 Ind: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
PROC7 Ind	
P75/TRA = 0.89	
B16-75 Brush/roller painting of boats with antifoulant - Copper PROC 10 Prof P75/TRA = 0.86	 PROC 10 Prof: OK LEV not applicable: OK Gloves applicable: OK (cotton sampling gloves were used for analysis, worn under protective gloves) No changes in TRA estimate for this scenario.
B16-41 Scooping, weighing and dumping of solid product – 15 kg zinc stearate	 PROC 8a Prof: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
PROC 8a Prof	
P75/TRA = 0.69	

Reference, Scenario & Original P75/TRA values	Observations
B16-40 Bag opening, scooping and weighing product, dumping in bin	 PROC8a Pro: OK LEV not applicable: OK Gloves not applicable: OK Duration modifier was applied in the original TRA estimate: OK No changes in TRA estimate for this scenario.
PROC8a Pro P75/TRA = 0.65	
B16-7 Spray painting of antifouling on ship - Copper	 PROC 11 Prof: OK (no 'Industrial' level of controls applicable to this scenario) LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
PROC 11 Prof	
P75/TRA = 0.58	
B16-51 Handling of treated wood – Vacuum pressure water-based method - Arsenic	 PROC 13 Ind: OK LEV not applicable: OK Gloves applicable: OK Concentration modifier < 1%: OK No changes in TRA estimate for this scenario.
PROC 13 Ind	
P75/TRA = 0.55	
B16-85 Loading tank truck at terminal PROC8b Pro	 Report not available; not reviewed (industry delivered data company A, 2009, as cited by Marquart et al., 2017) Duration modifier was applied in the original TRA estimate. No changes in TRA estimate for this scenario.
P75/TRA = 0.53	

Reference, Scenario & Original P75/TRA values	Observations
B16-42 Filling packages with products containing Butoxyethoxy ethanol (handling empty packages, filling and closing) PROC 8a Ind	 PROC 8a Ind: OK LEV not applicable: OK Gloves applicable: OK No changes in TRA estimate for this scenario.
P75/TRA = 0.52	
B16-61 Dipping objects in baths of NMP	 PROC 13 Ind: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
PROC 13 Ind	
P75/TRA = 0.52	
B16-109 Energy provider operator at loading bay (heavy fuels oils - Phenantrene)	 PROC 8a Ind: OK (note operators perform various tasks: sample collection, tank dipping, cleaning activities) LEV not applicable: OK Gloves applicable: OK No changes in TRA estimate for this scenario.
PROC 8a Ind	
P75/TRA = 0.36	
B16-17 Sand blasting (Cu)	 PROC 11: OK LEV not applicable: OK Gloves applicable: OK Duration modifier was applied in the original TRA estimate: OK
PROC 11	No changes in TRA estimate for this scenario.
PROC 8a Ind P75/TRA = 0.52 B16-61 Dipping objects in baths of NMP PROC 13 Ind P75/TRA = 0.52 B16-109 Energy provider operator at loading bay (heavy fuels oils - Phenantrene) PROC 8a Ind P75/TRA = 0.36 B16-17 Sand blasting (Cu) PROC 11 P75/TRA = 0.53	 PROC 13 Ind: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario. PROC 8a Ind: OK (note operators perform various tasks: sample collection, tank dipping, cleaning activities) LEV not applicable: OK Gloves applicable: OK No changes in TRA estimate for this scenario. PROC 11: OK LEV not applicable: OK Gloves applicable: OK Gloves applicable: OK No changes in TRA estimate for this scenario.

Reference, Scenario & Original P75/TRA values B16-10 Rolling application (dichlofluanid)	Observations PROC 10 Ind: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
PROC 10 Ind	
P/5/1KA = 0.28	PROC8b Ind: OK
Packing of product, mostly automated (supervision); some contact during breakdowns and changing of big- bags	 LEV applicable: OK (the filling operation is equipped with an extract ventilation system; note that for big-bag filling there is some direct contact during the changing of the big-bags, however this only involves a limited period of time and is rotating over the four workers per shift.) Gloves applicable: OK (gloves are worn during the majority of the shift time (supervision automated process (packing robot); repairs after breakdown; filling of big-bags: attaching big-bag to/removing from filling spout) No changes in TRA estimate for this scenario.
PROC8b Ind	
P75/TRA = 0.22 B16-79 Preparing and spraying DDT formulation PROC11 Pro P75/TRA = 0.21	 PROC11 Pro: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.

Reference, Scenario & Original P75/TRA	Observations
values	
B16-8 Large scale wiping of biocide	 PROC19 Pro: OK LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
PROC19 Pro	
P75/TRA = 0.15	
B16-6 Biocide mixing	 PROC15 Pro: OK (working with small amounts of chemicals, so PROC selection is OK; difficult to assign setting (ind/pro) based on available info (hospital/laboratory); industrial setting could be more likely but this would have no impact on outcome)
PROC15 Pro	 LEV not applicable: OK Gloves not applicable: OK No changes in TRA estimate for this scenario.
P75/TRA = 0.08	
B16-114	PROC10 Pro: OKLEV not applicable: OK
Spreading materials with comb (silkscreen printing)	 Gloves applicable: the Task Force disagree with the assignment of gloves as RMM in this scenario. For the P75 derivation, the data on potential exposure rate were used. The Task Force has removed the use of gloves as modifier. This change leads to a P75/TRA ratio of 0.02
PROC10 Pro	
P75/TRA = 0.08	

B16-46 Disinfection with spray pistol or lance	 PROC11 Pro: OK LEV not applicable: OK Gloves not applicable: OK Concentration modifier of 0.1: OK No changes in TRA estimate for this scenario.
PROC11 Pro	
P75/TRA = 0.05	

APPENDIX B: REVISED TRA WORKER MODULE LOOK-UP TABLES

Revised look-up tables for inhalation exposure (industrial and professional). The changes are highlighted in red bold font.

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
1	Use in closed process, no likelihood of exposure	yes	High			n/a	n/a
	(solids)	no		0.01	0.1		
	mg/m ³	yes	Modorato			n/a	n/a
		no	WOUCHALE	0.01	0.01		
		yes	Low			n/a	n/a
		no	LOW	0.01	0.01		
	(volatiles)	yes	High			n/a	n/a
	ppm	no	riigii	0.01	0.1		
		yes	Moderate			n/a	n/a
		no	Moderate	0.01	0.01		
		yes	Low			n/a	n/a
		no	LOW	0.01	0.01		
		yes	- Very Low			n/a	n/a
		no	Vory Low	0.01	0.01		
		_					
2	Use in closed, continuous process with occasional controlled exposure	yes	High			90	80
	(solids)	no		1	5		
	mg/m ³	yes	Madarata			90	80
		no	Wouerale	0.5	1		
		yes	Low			90	80
		no	LOW	0.01	0.01		
	(volatiles)	yes	High			90	80
	ppm	no	riigii	25	50		
		yes	Moderate			90	80
		no	wouchate	5	20		
		yes	Low			90	80
		no	LOW	1	5		
		yes	VoryLow			90	80
		no	Very LOW	0.1	0.1		

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
3	Use in closed batch process (synthesis or formulation)	yes	High			90	80
	(solids)	no		1	5		
	mg/m ³	yes	Madarata			90	80
		no	Moderate	1	1		
		yes	Low			90	80
		no	LOW	0.1	0.1		
	(volatiles)	yes	High			90	80
	ppm	no	riigii	50	100		
		yes	Modorato			90	80
		no	Moderate	10	25		
		yes	Low			90	80
		no	LOW	3	3		
		yes	Vondow			90	80
		no	Very LOW	0.1	0.1		

4	Use in batch and other process (synthesis) where opportunity for exposure arises	yes	High			90	80
	(solids)	no		25	50		
	mg/m ³	yes	Modorato			90	80
		no	Moderate	5	5		
		yes	Low			90	80
	no	no	LOW	0.5	1		

(volatiles)	yes	Lliab			90	80
ppm		no	nigii	100	250		
		yes	Madarata			90	80
		no	WOUCHALE	20	50		
	yes no	yes	1			90	80
		no	LOW	5	10		
		yes	Vondow			90	80
		no	very Low	0.1	0.1		

5	Mixing or blending in batch processes (multistage and/or significant contact)	yes	High			90	80
	(solids)	no		25	50		
	mg/m ³	yes	yes			90	80
		no	Woderate	5	5		
		yes	- Low			90	80
		no		0.5	1		

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
	(volatiles)	yes	High			90	80
	ppm	no	riigii	250	500		
		yes	Moderate			90	80
		no	wouldtate	50	100		
		yes	Low			90	80
		no	LOW	5	10		
		yes	Vorulow			90	80
		no		0.1	0.1		
6	Calendering operations	yes	High			90	80
	(solids)	no		25	50		
	mg/m ³	yes	Madarata			90	80
		no	Wouerale	5	5		
		yes	Low			90	80
		no	LOW	0.1	1		
	(volatiles)	yes	High			90	80
	ppm	no	High	250	500		
		yes	Madarata			90	80
		no	woderate	50	100		
		yes	Low			90	80
		no	LOW	5	10		
		yes	Vonulow			90	80
		no	Very LOW	0.1	0.1		

7	Industrial spraying	yes	High			90	n/a
	(solids)	no		100	n/a		
	mg/m ³	yes	Moderate			90	n/a
		no		20	n/a		
		yes	Low			90	n/a
		no	LOW	1	n/a		
	(volatiles)	yes	- High			90	n/a
	ppm	no		500	n/a		
		yes				90	n/a
		no	moderate	250	n/a		
		yes	Low			90	n/a
	-	no	LOW	100	n/a		
		yes	Verylow			90	n/a
		no	Very LOW	100	n/a		

8aTransfer of chemicals from/to vessels/large containers at non dedicated facilitiesyesHigh9080(solids)no 50 50 $$	PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	8a	Transfer of chemicals from/to vessels/large containers at non dedicated facilities	yes	High			90	80
mg/m³ yes no Moderate 90 80 no 5 10		(solids)	no		50	50		
no Modelate 5 10 yes Low 90 80 no 0.5 0.5 (volatiles) yes 400 ppm no 90 No 250 500		mg/m ³	yes	Madarata			90	80
yes no Low 90 80 no 0.5 0.5 0.5 (volatiles) yes ppm High 250 500			no	WOUCHALE	5	10		
no 0.5 0.5 (volatiles) yes 400 400 80 ppm no 400 500 80			yes	Low			90	80
yes High 90 80 ppm no 250 500			no	LOW	0.5	0.5		
yes 90 80 ppm no 250 500								
ppm no 250 500		(volatiles)	yes	High			90	80
		ppm	no	riigii	250	500		
yes 90 80			yes	Moderate			90	80
no 50 100			no	Moderate	50	100		
yes 90 80			yes	Low			90	80
no 10 25			no	LOW	10	25		
yes yerv low 90 80			yes	Very Low			90	80
no 0.1 0.1			no		0.1	0.1		

8b	Transfer of chemicals from/to vessels/large containers at dedicated facilities	yes	High			90	80
	(solids)	no		25	50		
	mg/m³	yes	Modorato			90	80
		no	wouerate	1	5		
		yes	Low			90	80
		no	LOW	0.1	0.5		

	(volatiles)	yes	High			90	80
	ppm	no	nigii	150	250		
		yes	Madarata			90	80
		no	woderate	25	50		
		yes	Low			90	80
		no	LOW	5	10		
		yes	Vorulou			90	80
	-	no	Very Low	0.1	0.1		

9	Transfer of chemicals into small containers (dedicated filling line)	yes	High			90	80
	(solids)	no		20	20		
	mg/m ³	yes	Madarata			90	80
		no	Moderate	5	5		

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
		yes	Low			90	80
		no	LOW	0.1	0.5		
	(volatiles)	yes	Llink			90	80
ppm		no	піgri	200	250		
		yes	Madamata			90	80
		no	woderate	50	100		
		yes	Laur			90	80
		no	LOW	5	10		
		yes	Mamilari			90	80
		no	very Low	0.1	0.1		

10	Roller application or brushing	yes	High			90	80
	(solids)	no		10	10		
	mg/m ³	yes	Madavata			90	80
		no	Moderate	5	5		
		yes	Low			90	80
		no	LOW	0.5	0.5		

(volatiles)	yes	Lliab			90	80
ppm	no	nign	250	500		
	yes	Madarata			90	80
	no	Moderate	100	200		
	yes	1			90	80
	no	LOW	10	25		
yes no	yes	Vorulow			90	80
	no	Very Low	0.1	0.1		

11	Non-industrial spraying	yes	High			n/a	80
	(solids)	no		n/a	200		
	mg/m ³	yes	Modorato			n/a	80
		no	Moderate	n/a	20		
		yes	Low			n/a	80
		no	LOW	n/a	1		
	(volatiles)	yes	High			n/a	80
	ppm	no	riigii	n/a	1000		
		yes	Modorato			n/a	80
		no	Moderate	n/a	500		
		yes	Low			n/a	80
		no	Low	n/a	100		

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
		yes	Vondou			n/a	80
		no	- Very Low	n/a	100		
12	Use as a blowing agent	yes	High			n/a	n/a
	(solids)	no		n/a	n/a		
	mg/m ³	yes	Moderate			n/a	n/a
		no	Moderate	n/a	n/a		
		yes	Low			n/a	n/a
		no		n/a	n/a		
	(volatiles)	yes	High			90	80
	ppm	no	Ŭ	100	500		
		yes	Moderate			90	80
		no		20	100		
		yes	Low		10	90	80
		no		2	10		
		yes	Very Low		10	90	80
		no		2	10		
13	dipping and pouring	yes	High			90	80
	(solids)	no		5	5		
	mg/m ³	yes	Moderate			90	80
		no		1	5		
		yes	Low			90	80
		no		0.1	0.5		
	(
		yes	High	250	250	90	80
	ррп	10		250	200	00	80
		yes	Moderate	50	100	90	80
				50	100	00	80
			Low	10	10	90	80
		Ves		10	10	90	80
			Very Low	0.1	0.1	50	00
				0.1	0.1		
14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	yes	High			90	80
	(solids)	no		10	50		
	mg/m ³	yes				90	80

1

Moderate

no

5

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
			Low			90	80
		no	LOW	0.1	1		
(volatiles)							
		yes	High			90	80
	ppm	no	Figh	250	500		
		yes	Modorato			90	80
		no	WOUEFale	50	100		
		yes	Low			90	80
		no	LOW	5	10		
	- -	yes	Vondow			90	80
		no	very Low	0.1	0.1		

15	Use of laboratory reagents in small scale laboratories	yes	High			90	80
	(solids)	no		5	5		
	mg/m ³		Madanata			90	80
		no	Moderate	0.5	0.5		
		yes	Low			90	80
		no	LOW	0.1	0.1		

(volatiles)	yes	High			90	80
ppm	no	підп	50	50		
	yes	Madarata			90	80
	no	Woderale	10	10		
	yes	Low			90	80
	no		5	5		
	yes	Vonulow			90	80
-	no	very Low	0.1	0.1		

16	Using material as fuel sources (limited exposure to unburned product to be expected)	yes	High			90	80
	(solids)	no		10	50		
	mg/m ³	yes	Modorato			90	80
		no		5	20		
		yes	Low			90	80
		no	Low	0.1	5		
	(volatiles)	yes	High			90	80
	ppm	no	riigii	25	50		
		yes	Modorato			90	80
		no	wouerate	5	10		
		yes	Low			90	80

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
		no		1	1		
		yes	Vondow			90	80
		no	very Low	0.1	0.1		
17	Lubrication at high energy conditions and in partly open process	yes	High			90	80
	(solids)	no		50	200		
	mg/m ³	yes	Moderate			90	80
		no	Moderate	20	50		
		yes	Low			90	80
		no		1	10		
	(volatiles)	yes	High		500	90	80
	ppm	no		100	500		80
		yes	Moderate	50	200	90	00
				50	200	90	80
			Low	20	50	50	00
		ves		20	00	90	80
		no	Very Low	20	50		
18	Greasing at high energy conditions	yes	High			90	80
	(solids)	no		50	200		
	mg/m ³	yes	Moderate			90	80
		no	Woderate	20	50		
		yes	Low			90	80
		no		1	5		
	<i></i>						
	(volatiles)	yes	High			90	80
	ppm	no		100	500		
		yes	Moderate	50	000	90	80
				50	200	00	80
		yes	Low	20	50	90	00
		Ves		20	00	90	80
			Very Low	20	50		
				_0			
19	Hand-mixing with intimate contact (only PPE available)	yes	High			90	80
	(solids)	no		25	50		
	mg/m ³	yes	Modorato			90	80
		no	woderate	5	5		

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
		yes	Low			90	80
		no	LOW	0.5	0.5		
	(volatiles)	yes	High			90	80
ppm		no	nıgri	250	500		
		yes	Madarata			90	80
		no	Moderate	50	100		
		yes	Laur			90	80
		no	LOW	10	25		
		yes				TRA provides es	stimate of 0.1ppm
		no	very Low	10	25	when LEV applied	
20	Heat and pressure transfer fluids (closed systems) in dispersive use	yes	High			n/a	80
((solids)	no		n/a	5		

mg/m ³	yes	Modorato			n/a	80
	no	Moderate	n/a	1		
	yes	Low			n/a	80
	no	LOW	n/a	0.01		
(volatiles)	yes	- High -			n/a	80
ppm	no		n/a	50		
	yes	Modorato			n/a	80
	no	Moderate	n/a	20		
	yes	Low			n/a	80
	no	LOW	n/a	5		
	yes				n/a	80

n/a

0.1

21	Low energy manipulation of substances bound in materials and/or articles	yes	High			90	80
	(solids)	no		10	20		
	mg/m ³	yes	Modorato			90	80
		no	woderate	3	5		
		yes	Low			90	80
		no	LOW	1	3		
	(volatiles)	yes	High			n/a	n/a
	ppm	no	riigii	n/a	n/a		
		yes	Moderate			n/a	n/a
		no	woderate	n/a	n/a		
		yes	Low			n/a	n/a

Very Low

no

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
		no		n/a	n/a		
		yes				n/a	n/a
		no	Very Low	n/a	n/a		
22	Potentially closed operations with minerals at elevated temperature	yes	High			90	n/a
	(solids)	no		10	n/a		
	mg/m ³	yes	Moderate			90	n/a
		no		3	n/a		
		yes	Low			90	n/a
		no		1	n/a		
	6						
	(volatiles)	yes	High			n/a	n/a
	ppm	no		n/a	n/a		
		yes	Moderate			n/a	n/a
		no		n/a	n/a		
		yes	Low			n/a	n/a
		no		n/a	n/a		
		yes	Very Low			n/a	n/a
		no		n/a	n/a		
23	Open processing and transfer of minerals at elevated temperature	yes	High			90	80
	(solids)	no		10	20		
	mg/m ³	yes				90	80
		no	Moderate	3	5		
		yes				90	80
		no	LOW	1	3		
	(volatiles)	yes	High			n/a	n/a
	ppm	no	nign	n/a	n/a		
		yes	Moderato			n/a	n/a
		no	Wouerate	n/a	n/a		
		yes	Low			n/a	n/a
		no	LOW	n/a	n/a		
		yes	VeryLow			n/a	n/a
		no		n/a	n/a		
24	High (mechanical) energy work-up of substances bound in materials and/or articles	yes	High			80	75
	(solids)	no		10	20		

PROC	Exposure scenario	LEV	Fugacity	Industrial exposure prediction	Professional exposure prediction	LEV effectiveness industrial (%)	LEV effectiveness professional (%)
	mg/m³	yes	Modorato			80	75
		no	WOUCHALE	3	5		
		yes	Low			80	75
		no	LOW	1	3		
	(volatiles)	yes	Lliab			n/a	n/a
	ppm	no	High	n/a	n/a		
		yes	Madavata			n/a	n/a
		no	woderate	n/a	n/a		
		yes	Law			n/a	n/a
		no	LOW	n/a	n/a		
		yes	Mamelau			n/a	n/a
		no	very Low	n/a	n/a		

25	Hot work operations with metals	yes	High			90	80
	(solids)	no		5	10		
	mg/m ³	yes	Modorato			90	80
		no	WOUCHALE	5	10		
		yes	Low			90	80
		no	LOW	5	10		
	(volatiles)	yes	High			n/a	n/a
	ppm	no	riigii	n/a	n/a		
		yes	Moderate			n/a	n/a
		no	Woderate	n/a	n/a		
		yes	Low			n/a	n/a
		no	LOW	n/a	n/a		
		yes	VeryLow			n/a	n/a
		no	VELY LOW	n/a	n/a		

PROC	Use	LEV	Reduction of dermal exposure due to LEV (%)	Initial dermal exposure (μg/cm²/day)	Exposed skin surface area (cm²)	Predicted dermal exposure (mg/kg/day)
4	Use in closed	Yes	0	10	040	0.034
1	of exposure	No	0	10	240	0.034
	Use in closed, continuous process	Yes	90	20	400	0.14
Z	with occasional controlled exposure	No	0	200	480	1.37
	Use in closed batch	Yes	90	20	040	0.07
3	process (synthesis or formulation)	No	0	200	240	0.69
	Use in batch and other process	Yes	90	100		0.69
4	(synthesis) where opportunity for exposure arises	No	0	1000	480	6.86
F	Mixing or blending in batch processes	Yes	90	200	480	1.37
Э	5 (multistage and/or significant contact)	No	0	2000	480	13.71
6	6 Calendering operations	Yes	90	200	960	2.74
0		No	0	2000	300	27.43
7	Inductrial aproving	Yes	90	200	1500	4.29
	industrial spraying	No	0	2000	1300	42.86
8a	Transfer of chemicals from/to vessels/large	Yes	90	200	960	2.74
04	containers at non dedicated facilities	No	0	2000	000	27.43
Qh	Transfer of chemicals from/to vessels/large	Yes	90	100	060	1.37
dD	containers at dedicated facilities	No	0	1000	900	13.71
0	Transfer of chemicals into small	Yes	90	100	490	0.69
9	containers (dedicated filling line)	No	0	1000	480	6.86
	Roller application or	Yes	0	2000		27.43
10	brushing	No	0	2000	960	27.43
14	Non-industrial	Yes	n/a	n/a		n/a
11	spraying	No	n/a	n/a	n/a	n/a
10	Use as a blowing	Yes	90	10	240	0.03
12	agent	No	0	100	240	0.34

Revised look-up tables for dermal exposure (industrial). The changes are highlighted in red bold font.

PROC	Use	LEV	Reduction of dermal exposure due to LEV (%)	Initial dermal exposure (μg/cm²/day)	Exposed skin surface area (cm²)	Predicted dermal exposure (mg/kg/day)
12	Treatment of articles	Yes	90	200	480	1.37
15	pouring	No	0	2000	400	13.71
	Production of preparations or	Yes	90	50	400	0.34
14	articles by tabletting, compression, extrusion, pelletisation	No	0	500	480	3.43
15	Use of laboratory	Yes	90	10	240	0.03
	scale laboratories	No	0	100	240	0.34
40	Using material as fuel sources (limited	Yes	90	10	040	0.03
16	exposure to unburned product to be expected)	No	0	100	240	0.34
17	Lubricants at high energy conditions and	Yes	90	200	960	2.74
	in partly open processes	No	0	2000	900	27.43
18	18 Greasing at high energy conditions	Yes	90	100	960	1.37
		No	0	1000	500	13.71
19	Hand-mixing with	Yes	0	5000	1980	141.43
	PPE available)	No	0	5000	1000	141.43
20	Heat and pressure transfer fluids (closed	Yes	n/a	n/a	n/a	n/a
	systems) in dispersive use	No	n/a	n/a		n/a
21	Low energy manipulation of	Yes	90	10	1080	0. 28
21	materials and/or articles	No	0	100	1900	2.83
22	Potentially closed operations with	Yes	0	10	1980	0.28
	minerals at elevated temperature	No	90	100	1000	2.83
23	Open processing and transfer of	Yes	90	5		0.14
	minerals at elevated temperature	No	0	50	1980	1.41
04	High (mechanical) energy work-up of	Yes	80	20	1090	0.57
<u> </u>	materials and/or articles	No	0	100	1980	2.83
25	Hot work operations with metals	Yes	90	1	1980	0.03

PROC	Use	LEV	Reduction of dermal exposure due to LEV (%)	Initial dermal exposure (μg/cm²/day)	Exposed skin surface area (cm²)	Predicted dermal exposure (mg/kg/day)
		No	0	10		0.28

PROC	Use	LEV	Reduction of dermal exposure due to LEV (%)	Initial dermal exposure (μg/cm²/day)	Exposed skin surface area (cm²)	Predicted dermal exposure (mg/kg/day)
4	Use in closed	Yes	0	10	040	0.034
1	of exposure	No	0	10	240	0.034
	Use in closed, continuous process	Yes	80	40	400	0.27
2	with occasional controlled exposure	No	0	200	480	1.37
	Use in closed batch	Yes	80	40	040	0.14
3	formulation)	No	0	200	240	0.69
	Use in batch and other process	Yes	80	200		1.37
4	(synthesis) where opportunity for exposure arises	No	0	1000	480	6.86
F	Mixing or blending in batch processes	Yes	80	400	480	1.37
5	5 (multistage and/or significant contact)	No	0	2000		6.86
6	6 Calendering operations	Yes	80	400	960	2.74
0		No	0	2000	300	13.71
7	Industrial spraving	Yes	n/a	n/a	n/a	n/a
	industrial spraying	No	n/a	n/a	Π/a	n/a
8a	Transfer of chemicals from/to vessels/large	Yes	80	400	960	5.49
	containers at non dedicated facilities	No	0	2000		27.43
8b	Transfer of chemicals from/to vessels/large	Yes	80	200	960	2.74
00	containers at dedicated facilities	No	0	1000	300	13.71
0	Transfer of chemicals into small	Yes	80	200	490	1.37
9	containers (dedicated filling line)	No	0	1000	400	6.86
10	Roller application or	Yes	0	2000	000	27.43
10	brushing	No	0	2000	960	27.43
11	Non-industrial	Yes	80	1000	1500	21.43
	spraying	No	0	5000	1500	107.14
10	Use as a blowing	Yes	80	20	240	0.07
12	agent	No	0	100	240	0.34

Revised look-up tables for dermal exposure (professional). The changes are highlighted in red bold font.

PROC	Use	LEV	Reduction of dermal exposure due to LEV (%)	Initial dermal exposure (μg/cm²/day)	Exposed skin surface area (cm²)	Predicted dermal exposure (mg/kg/day)
13	Treatment of articles	Yes	80	400	480	2.74
15	pouring	No	0	2000	400	13.71
14	Production of preparations or	Yes	80	100	400	0.69
14	compression, extrusion, pelletisation	No	0	500	480	3.43
15	Use of laboratory reagents in small	Yes	80	20	240	0.07
	scale laboratories	No	0	100	240	0.34
40	Using material as fuel sources (limited	Yes	80	20	0.40	0.07
16	exposure to unburned product to be expected)	No	0	100	240	0.34
17	Lubricants at high energy conditions and	Yes	80	400	960	5.49
	in partly open processes	No	0	2000	300	27.43
18	Greasing at high	Yes	80	200	960	2.74
energy conditions	No	0	1000	300	13.71	
19	Hand-mixing with	Yes	0	5000	1980	141.43
	PPE available)	No	0	5000	1000	141.43
20	Heat and pressure transfer fluids (closed	Yes	80	50	480	0.34
20	systems) in dispersive use	No	0	250	400	1.71
04	Low energy manipulation of	Yes	80	20	1000	0.57
21	materials and/or articles	No	0	100	1980	2.83
22	Potentially closed operations with	Yes	n/a	n/a	n/a	n/a
	minerals at elevated temperature	No	n/a	n/a	n/u	n/a
23	Open processing and transfer of	Yes	80	10	1980	0.28
20	minerals at elevated temperature	No	0	50	1300	1.41
<u> </u>	High (mechanical) energy work-up of	Yes	75	25	4000	0.71
24	substances bound in materials and/or articles	No	0	100	1980	2.83
25	Hot work operations with metals	Yes	80	2	1980	0.06

PROC	Use	LEV	Reduction of dermal exposure due to LEV (%)	Initial dermal exposure (μg/cm²/day)	Exposed skin surface area (cm²)	Predicted dermal exposure (mg/kg/day)
		No	0	10		0.28

ABBREVIATIONS

BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Cefic	European Chemical Industry Council
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
EASE	Estimation and Assessment of Substance Exposure model
EC	European Commission
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
GM	Geometric Mean
GSD	Geometric Standard Deviation
HSE	Health and Safety Executive
IND	INDustrial
LEV	Local Exhaust Ventilation
LRI	Long-range Research Initiative
MAE	Mean Absolute Error
OEL	Occupational Exposure Limit
ОС	Operating Conditions
PROC	PROcess Category
PROF	PROFessional
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RCR	Risk Characterisation Ratio
RMM	Risk Management Measures
RPE	Respiratory Protective Equipment

SEG	Similar E	Exposure	Group

- TF Task Force
- TRA Targeted Risk Assessment
- TWA Time-Weighted Average
- USEPA United States Environmental Protection Agency

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Note: All websites were accessed in May 2023

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Acknowledgment

The TF is very grateful to those authors of the TRA validation studies who provided the data supporting information. The TF is further grateful to Gerald Bachler (Dupont; new TF member since April 2023) for his critical review of this report.

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