Final report

Analysis of worker exposure in manufacture and use of formaldehyde in Europe, including downstream applications

TNO Triskelion BV
Utrechtseweg 48
3704 HE Zeist
PO Box 844
3700 AV Zeist
www.triskelion.nl

E-mail
selma.dieperink@tno.triskelion.nl

Direct dialling
+31 88 866 50 27

Date	26 April 2013
Report number	V20362
Author(s)	Babs van Manen-Vernooij Hans Marquart Selma Dieperink-Hertsenberg
Number of pages	79 (incl. appendices)
Number of appendices	2
Sponsor	Formacare Dr. P. Hope Av E. van Nieuwenhuyse 4 B-1160 BRUSSELS Belgium
Project name	Analysis of the most appropriate Risk Management Option for Formaldehyde
Project number	093.20380

Executive summary

Worker exposure to formaldehyde in European industry and professional uses has been assessed in the scope of the determination of the most appropriate Risk Management Option for formaldehyde. Only those exposure situations are included that are the result of the actual use of formaldehyde or a formaldehyde based products and that are relevant for the REACH assessment of the substance. Exposures due to e.g. combustion or products or articles and worker exposures due to the use of cosmetics or biocides (including formaldehyde donors) are excluded from this study.

Where possible, conditions and risk management measures that lead to safe use of formaldehyde are described preferably based on recent measured data provided by the manufacturers and downstream users of formaldehyde. This data was gathered largely via specific questionnaires to ensure sufficient contextual information to enable a useful analysis. When insufficient recent measured data was available, an attempt was made to indicate safe conditions and relevant risk management measures based on recent high quality literature data. If this was also not possible, model estimates were made. In this scope safe use is defined by exposures below the DNELs that have been set by the formaldehyde REACH consortium: 0.5 mg/m^3 for long term inhalation exposure and 1 mg/m^3 for short term inhalation exposure.

For manufacture and a number of highly relevant downstream uses sufficient measured data were available to evaluate exposures in relation to job groups and (a number of) conditions and risk management measures. For the use in paints (both industrial and professional) sufficient high quality literature data was available. For other downstream uses the conditions and risk management measures leading to safe use are based on model estimations.

The results of the study are summarized in the following overview.

Life cycle stage	Identified use	Risk assessment		
		User	Literature	Model
Manufacture	Manufacture + aq. Solutions	X		
	Manufacture chemicals / resins / polymers	X		
Formulation	Formulation	X		
Industrial end use	Prod. Wood based materials	X		
	Prod. Fertiliser granules			X
	Prod. Rubber	X		
	Prod. Foams			X
	Prod. Leather			X
	Prod. Paper			X
	Impregnation of Textile			X
	Prod. Bonded particulates			X
	Prod. Bonded fibers/mats			X
	Use Adhesives/coatings		X	
Professional end	Use Adhesives/coatings		X	
	Prod. Foams			X
	Use resin wood applications			X

[1] The colour coding has the following interpretation:

Green: exposure values or estimates are below the reference value and are sufficient to indicate safe use;
Light green: Exposure values or estimates are below the reference value. Measured exposure values are however insufficient for sole basis of conclusions. Exposure estimates demonstrate safe use assuming specific risk management measures.
Grey: Part of the data are below and part of the data are above the reference value.
Orange: Exposure estimates are below the reference value, however, very stringent risk management measures need to be taken to reach these values.
Red: Exposure values presented in literature are above the reference value.
The data source used for defining conditions and risk management measured leading to safe use is indicated by a thick border around the relevant cell.

For manufacturing and production of wood based materials the conclusions have been specified for a number of subgroups with specific conditions and risk management measures.

In several cases, specifically for a number of downstream uses, specific risk management measures are needed to ensure exposures below the DNEL, e.g. reduction of the duration of exposure or the use of respiratory protection for specific activities. However, these risk management measures are considered to be feasible. For the professional production of foams and the professional use of resins in wood applications very stringent risk management measures are calculated to be needed to ensure safe use, such as strict reduction of duration of exposure to less than one hour per day combined with respiratory protection.

This study shows that exposures are shown to be below the DNELs of 0.5 mg/m^3 (long term) and 1 mg/m^3 (short term) in manufacture and several downstream uses and can be estimated to be below these DNELs in other downstream uses, provided that the appropriate conditions and risk management measures are in place. This implies that those companies that do not yet have these conditions or risk management measures in place may need to implement them to ensure that they have exposures below the DNELs.

Table of contents

Executive summary 2
1 Introduction 8
2 Uses and exposure scenarios 9
3 Methodology 12
3.1 Generally 12
3.2 Hazard 12
3.3 Worker exposure 12
4 Results 17
4.1 Worker exposure data and workplace concentrations provided by Formaldehyde manufacturers 17
4.2 Worker exposure data and workplace concentrations provided by Formaldehyde based resin / chemical producers 22
4.3 Worker exposure data and workplace concentrations provided by wood panel producers 28
4.4 Worker exposure data and workplace concentrations provided by other downstream users 36
4.5 Literature data on the use of Formaldehyde by downstream users 48
4.6 Exposure modeling on the use of Formaldehyde formulations by downstream users 55
5 Risk assessment 57
6 Discussion 64
7 References 69
Annex I. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products 71
Annex II. Worker exposure estimations for downstream use of Formaldehyde based products 76

Table 1. Formaldehyde use in Europe 9
Table 2. Criteria for evaluation of the usefulness of Literature sources 15
Table 3. Worker exposure to formaldehyde in process control at manufacturing sites of formaldehyde.......... 19
Table 4. Formaldehyde worker exposure during maintenance/cleaning of the manufacturing process 20
Table 5. Formaldehyde worker exposure during transfer of Formaldehyde and Resins 21
Table 6. Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins 22
Table 7. Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process 24
Table 8. Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process 25
Table 9. Formaldehyde worker exposure during management as part of Resin / chemicals manufacturing process 25
Table 10. Formaldehyde worker exposure during maintenance/cleaning of the resin / chemicals manufacturing process 26
Table 11. Formaldehyde worker exposure during transfer of solid resin 27
Table 12. Formaldehyde worker exposure during production of wood based panels.......... 32
Table 13. Formaldehyde worker exposure during paper impregnation and lamination of wood based panels 33
Table 14. Formaldehyde worker exposure during sanding & sawing of wood based panels 34
Table 15. Formaldehyde worker exposure during maintenance & cleaning in the wood panel industry 35
Table 16. Formaldehyde worker exposure during logistics & laboratory activities in the wood panel industry 36
Table 17. Formaldehyde exposure levels provided by Formulators of Formaldehyde based products 37
Table 18. Formaldehyde exposure levels provided by producers of Fertilizer granules 39
Table 19. Formaldehyde worker exposure during weighing and loading during Tyre & Rubber manufacturing.......... 40
Table 20. Formaldehyde worker exposure during the mixing part of Tyre & Rubber manufacturing 41
Table 21. Formaldehyde worker exposure during the shaping part of Tyre & Rubber manufacturing42
Table 22. Formaldehyde worker exposure during the curing part of Tyre & Rubber manufacturing.. 42
Table 23. Formaldehyde worker exposure during the Finishing part of Tyre & Rubber manufacturing 43
Table 24. Formaldehyde exposure levels provided by Leather producers.......... 46
Table 25. Formaldehyde exposure levels provided by Foam producers 47
Table 26. Formaldehyde exposure levels provided by Fibers/Mats producers.......... 47
Table 27. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products for Paper production. 49

Table 28. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products for Paper production. 50
Table 29. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based resins in wood applications 52
Table 30. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products for production of Bonded fibers or fiber mats 53
Table 31. Formaldehyde exposure levels published in literature associated with the application of Formaldehyde based adhesives and coatings 54
Table 32. Summary of results worker exposure risk assessment based on available data sources 57

1 Introduction

Formaldehyde (CAS-number 50-00-0) is an important industrial chemical that is mainly used in the production of adhesives or binder resins. It has been registered under the REACH-regulation in 2010. In the Chemical Safety Report (CSR) of 2010 the conclusions on the safe use of workers were not yet founded by workplace measured data. Therefore measured data have been collected from several use sectors and available literature was reviewed for data on formaldehyde air concentrations on the workplace. Data were compared to the DNEL for workers of 0.5 mg/m^3 (0.4 ppm) for long term exposure and 1 mg/m^3 (0.8 ppm) for short term exposure . This report describes the main findings.

2 Uses and exposure scenarios

Table 1 visualizes the manufacturing and use of Formaldehyde in Europe based on the CSR submitted in 2010. Based on discussions with the steering committee some adaptations are made. The life cycle of Formaldehyde includes manufacturing of Formaldehyde and Formalin, Formulation of Formaldehyde based products and subsequent industrial and professional use of both Formalin and other Formaldehyde based products. Identified uses are clustered based on Formaldehyde content and life cycle stage as those are important factors for exposure.

Table 1. Formaldehyde use in Europe

Life cycle stage	Exposure Scenario	Identified use	REACH Use descriptors			
			PC	SU	PROCs	AC
Manufacturing	Manufacturing of Formaldehyde + aq. formaldehyde solutions and use as intermediate	Manufacturing of Formaldehyde + aq. formaldehyde solutions	NA	3, 8, 9, 10, 12	1, 2, 3, 4, 5, 6, 8a, 8b, 9, 14, 15	NA
		Manufacturing of chemicals / resins / polymers				
Formulation	Formulation of preparations	Formulation	NA	3, 10	1, 2, 3, 4, 5, 6, 8a, 8b, 9, 14, 15	NA
Industrial End use	Industrial use of preparations containing formaldehyde up to 60%	Production of fertilizer granules	NA	3, 8	1, 2, 8a, 8b [1)]	NA
	Industrial use of preparations containing formaldehyde up to 5%	Production of bonded particulates	NA	2a, 3, 5, 8, 9, 10, 11, 12, 13, 14, 17, 19	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 16, 21, 22, 23, 24, 25	NA
		Use of adhesives and coatings				
		Production of rubber				
		Production of leather				
		Production of foams				

Life cycle stage	Exposure Scenario	Identified use	REACH Use descriptors			
			PC	SU	PROCs	AC
	Industrial use of preparations containing formaldehyde up to 2.5%	Production of woodbased materials Production of impregnated paper Production of bonded fibers or fiber mats Impregnation of textiles Production of paper	NA	3, 5, 6a, 6b, 10, 11, 12, 13, 18, 19	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 16, 21, 22, 23, 24, 25	NA
	Industrial use of preparations containing formaldehyde up to 1.5%	Production of bonded particulates Use of adhesives and coatings Production of rubber Production of leather Production of foams	NA	2a, 3, 5, 8, 9, 10, 11, 12, 13, 14, 17, 19	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 16, 21, 22, 23, 24, 25	NA
	Industrial use of preparations containing formaldehyde up to 1%	Production of woodbased materials Production of impregnated paper Production of bonded fibers or fiber mats Impregnation of textiles Production of paper	NA	3, 5, 6a, 6b, 10, 11, 12, 13, 18, 19	1, 2, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 24	NA
Professional End Use	Professional use of preparations containing formaldehyde up to 1.5%	Application of adhesives and coatings Production of foams	8, 9a, 13, 31, 35, 39	22	5, 8a, 8b, 10, 11, 13, 15, 16, 19, 21, 22, 23, 24, 25	NA

Life cycle stage	Exposure Scenario	Identified use	REACH Use descriptors			
			PC	SU	PROCs	AC
	Professional use of preparations containing formaldehyde up to 1%	Professional use of resins in wood applications		22	5, 8a, 8b, 10, 15	
Consumer use	Consumer use of formaldehyde based products	Consumer use of formaldehyde based products	1, 3, 8, 9a, 9b, 9c, 13, 15, 18, 21, 23, 31, 32, 35, 37, 39	21	NA	NA (free formaldehyde < 0.1%)

[1)] PROCs 8a and 8b have been added compared to the table in the CSR.

3 Methodology

3.1 Generally

In addition to intentional industrial production, formaldehyde is produced unintentionally from natural sources and from human activities. Combustion processes account for most of the formaldehyde entering the environment. Combustion sources include automobiles and other internal combustion engines, power plants, incinerators, refineries, forest fires, wood stoves, and cigarettes. Photochemical oxidation of hydrocarbons and other precursors released from combustion processes can be a significant indirect source of formaldehyde. Formaldehyde may also be produced in the atmosphere by the oxidation of methane. Formaldehyde is also formed in the early stages of decomposition of plant residues in soil (NTP 2010).

Due to this unintentionally formaldehyde sources, workers are exposed to a background concentration of Formaldehyde. The measurement methods do not discriminate between the source of Formaldehyde. Hence, worker exposure measurements represent background Formaldehyde exposure combined with exposure due to manufacturing or use of Formaldehyde based products. The risk assessment focuses on Formaldehyde exposure due to manufacturing or use of Formaldehyde based products and does not take processes into account that does not make use of Formaldehyde based products.

3.2 Hazard

The quantitative worker exposure risk assessment in this study includes inhalation exposure data only as this was the primary focus of this study. Dermal exposure has been estimated with ECETOC TRA version 2 in the CSR. A revision of those estimates, e.g. by using ECETOC TRA version 3, has not been a part of this study as the critical health effect concerns inhalation exposure only.
The DNELs established by the Formaldehyde consortium were used as reference values for comparison with measured, literature and/or modeled exposure values:

- Long-term inhalation DNEL = 0.5 mg/m^3
- Short-term inhalation DNEL = 1 mg/m^3.

3.3 Worker exposure

Methods

Worker exposure assessment is based on data sources according to the following hierarchy: actual measured data from manufacturers and present users is preferred, followed by literature data and model estimations. The advantage of actual measured data from manufacturers and present users is the fact that this data can include relevant contextual information that allows analysis of *e.g.* differences between situations and the fit of the measured situation with specific Operational Conditions (OC) and Risk Management Measures (RMM) used in the REACH Exposure Scenarios.

Literature data often does not present extensive contextual information and is therefore usually much more difficult to evaluate or to link to specific OC and RMM.

Worker exposure data and workplace concentrations provided by users

Data collection

In order to structure the process of data gathering, a spreadsheet was composed and distributed including all relevant determinants of worker exposure (*e.g.* sampling information, product information, information on the operational conditions and risk management measures). The distribution was done (largely) via the relevant industry sectors of manufacturers and users of formaldehyde. Submission of data was directly to TNO Triskelion to ensure confidentiality of information. The process of data gathering was followed up by mail and telephone and submitters of information were assisted in case of technical questions. A completeness check was performed on all datasets. Submitters of information were asked to complete information if key exposure determinants were missing *(e.g.* use description, personal/stationary measurement, unit of measurement, sampling duration).

Data processing

All datasets were anonymised and merged in a separate Excel database per industry sector. Amongst the data provided, the measurement unit varied between mg/m^3, µg/m^3 and ppm. As the inhalation DNEL is expressed in mg/m^3, all values were expressed or recalculated to this unit. Conversion was based on the following formula; mg/m^3= (ppm value)(molecular weight)/24.45
A molecular weight of 30.0263 g/mol was used as presented in the CSR. The constant 24.45 refers to the volume (liters) of a mole (gram molecular weight) of a gas or vapour when the pressure is at 1 atmosphere and 20°C. (http://www.skcinc.com/converter/converter.asp)
All measured values below the detection limit were set to one-half of the limit of detection which is considered reasonable since the true concentration must be somewhere between zero and the limit of detection (Hornung and Reed, 1990). Data selection included a check on actuality, representativeness and key exposure determinants. Data more than 20 years old or data missing key exposure determinants (*e.g.* type of measurement, sampling duration) were excluded from further analysis. Aggregated and/or calculated data, for which no original data points could be submitted, were excluded to ensure data analysis on raw individual data points. However, where aggregated or calculated data were submitted, submitters of information were asked to provide the raw data instead, if possible. Data representing unusual situations (e.g. double shift measurements) were excluded as well.
Measurements with a sampling duration less than 60 min were categorized as short term measurements. Long term measurements include all data with a corresponding measurement duration more than or equal to 60 minutes. This distinction is based on the assumption that exposure measurements with a duration less than 60 minutes have probably been taken to measure peak exposure events or specific activities, while it is very likely that measurements with a duration more than or equal to 60 minutes have been taken as part of normal activities and therefore represent 8 hour exposure.

Data analysis was performed according to a stepwise approach. Basic analysis included calculation of summary statistics for broad groups based on identified use, sampling duration and measurement type (e.g. personal or stationary). Data missing key exposure determinants (*e.g*. sampling duration) were excluded from basic analysis. During subsequent job group analysis, summary statistics were calculated for personal data job groups defined on contextual information provided in the spreadsheets. If safe use was not demonstrated for the total job group, relations between circumstances and exposure were investigated. Hence, summary statistics were calculated for job groups subdivided by determinants such as Formaldehyde content, location (indoor/outdoor), process enclosure and/or LEV. Subsequently, summary statistics were calculated using the data representing specific determinants. If safe use could not be demonstrated by data representing specific technical determinants, the possibility to conclude on safe use by the use of respiratory protection was investigated. In some cases, a lack of scenario information made it impossible to categorize the measurement in a job group category or determinants category. Those data were excluded from job group and/or determinants analysis.

Statistical analysis

Measurement data were checked for lognormality using IHSTAT version 2010. Because by far most of the data sets appeared to be (more or less) lognormally distributed, further calculations were based on a lognormal distribution characterized by a geometric mean (GM) and geometric standard deviation (GSD). In preparation of the calculation of GM and corresponding GSD values, the natural log (LN) of all measurement concentration was calculated. Excel version 2010 was used to calculate basic descriptive statistics including number of data, minimum and maximum values, geometric mean, geometric standard deviation, 90- and 95 percentile values. The 90- and 95 percentile values were not calculated directly with the EXCEL 'Percentile' function, because this function does not account for the general distribution of the data and therefore leads to very uncertain values, specifically for small data sets. Instead the calculated GM and GSD were used for calculating percentiles via the equation for the normal distribution.

In theory, short term exposure values should be high compared to long term values. If short term exposure values are relatively low, the 95^{th} percentile short-term value has also been estimated by multiplying the 90^{th} percentile long-term value with a factor 2 (REACH Guidance R14)

Risk assessment

Preferably, conclusions on safe use of formaldehyde are based on personal exposure data as stationary measurements should only be used if there is sufficient information provided to demonstrate how they reflect personal exposures or that they provide a conservative estimate of personal exposures. As a general guide, a reasonable worst case value should be used as the point estimate for comparison with the DNEL. The choice of value representing the reasonable worst case depends on the (knowledge of) the fit between the measured data and the exposure scenario and the variation in the measured data and the situations the data represent. For this analysis the 90th percentile of the measured data range is considered to constitute the 'reasonable worst case' estimate for long-term exposure. This relatively conservative percentile is chosen because of the variation in activities within the job groups and the variation in percentages of formaldehyde reported combined with the lack of detail on risk management measures in this analysis.

Furthermore, it is considered that the fact that the authorities have shown to be especially concerned about the risks of formaldehyde should best be answered by taking a relative conservative approach in the data analysis. By using a 90th percentile, it is taken into account that any long-term effect will be related to a combination of exposures over a longer period and not to a single high exposure. For short-term exposure, related to acute effects that occur after a single exposure, but that are not very severe (such as some lung and eye irritation), it is considered that the probability of these effects should be relatively low, i.e. although it may be impossible to ensure that such effects will never occur, the exposure should be kept so low that such effects will occur only occasionally. Therefore, for such short-term exposures in general the 95th percentile of the measured data range is considered to be a reasonable worst case (REACH guidance R14).

Workplace exposure data and workplace concentrations provided by literature

The literature databases Pubmed (http://www.ncbi.nlm.nih.gov/pubmed) and Scopus (http://www.scopus.com/home.url) were used to select literature representing occupational inhalation exposure to Formaldehyde. Literature was considered relevant if the publishing date was equal or less than 20 years back and data represented occupational exposure. Besides that, the source of Formaldehyde should be a Formaldehyde based product used at the workplace. Hence, natural sources of Formaldehyde and burning products were not considered relevant. Also, the use of formaldehyde as biocide or the exposure to formaldehyde due to the use of formaldehyde donors as biocide was considered not relevant, because these exposure are outside the domain of REACH. The usefulness of all relevant sources was judged based on the criteria described in **Table 2**.

Table 2. Criteria for evaluation of the usefulness of Literature sources

Criterion	Description
Actual	Sampling date less than 20 years old
Reliable	Information on key exposure determinants available
Representative	Data represent personal worker exposure Data are reasonable worst-case for European industry
Robust	Number of data is sufficient for robust exposure assessment

Literature sources with “Low” usefulness are considered indicative for worker exposure only. Sources with “Medium” usefulness were considered illustrative for worker exposure. In case of literature sources with Low or Medium usefulness, additional data sources are necessary to complete the exposure assessment. Literature sources of “High” usefulness were considered suitable as basis for exposure assessment. In order to compare the Formaldehyde exposure levels presented in literature, all exposure levels were converted to the unit mg/m^3 using the molecular weight of Formaldehyde. Subsequently, 90^{th} or 95^{th} percentile levels were calculated if GM and GSD values were available.

Workplace exposure estimations generated by using exposure models

Model estimations were performed in case of insufficient user data or literature data. Use descriptors described in **Table 1** were used as basis for calculations. Partial vapour pressure input values were calculated using the variant of the Lacy equation published by Walker (Krieger, 1964). Exposure estimations were performed for clusters of uses based on sector of use and formaldehyde content. Easy TRA version 3.5.0 (Jansen-Systems GmbH) with ECETOC TRA Version 3 built-in was used as basis for First Tier worker exposure estimations. Long-term and short-term exposure values calculated with ECETOC TRA represent the 75th percentile and 95th percentile values of the exposure distribution respectively. ECETOC TRA calculates short term exposure by multiplying the long term task exposure (without time restrictions) with a factor 4 (ECETOC, 2012). This approach is considered too conservative in case of time restrictions for the long term exposure route. In this study, short term exposure values are calculated by multiplying long term exposure values including time restrictions with a factor 4. Higher tier ART Version 1.0 estimations were performed for use of production processes using products with a Formaldehyde content of 60%. The upper limit of the interquartile range of the 75th percentile is considered the reasonable worst case value for long term worker exposure. This is a relatively conservative estimate of the 75th percentile, taking into account uncertainty in the calculation of the percentiles. Taking this uncertainty into account, the upper limit of the 75th percentile ART estimation is considered similar to a direct estimation of the 90th percentile value of the exposure distribution, where such uncertainty is not taken into account separately and the most likely estimate of the percentile is used. Estimations of the 95th percentile value of short-term exposure are calculated by multiplying the long-term ART estimation with a factor 2. The estimations are compared to the DNEL values in risk assessment.

4 Results

In the following sections, Formaldehyde exposure data provided by manufacturers and users are presented first. In a later part of the results literature data are presented were relevant, followed by model estimates. Formacare members manufacture Formaldehyde, use Formaldehyde as an intermediate and/or manufacture Formaldehyde based resins. This study distinguishes between worker exposure during manufacturing of Formaldehyde and manufacturing of Formaldehyde based resins/use as intermediate. Most Formacare members did however provide datasets with worker exposure values of both processes.

Exposure values presented in the tables are not corrected for the possible use of respiratory protection equipment (RPE) unless the use of this equipment is described in the scenario.

4.1 Worker exposure data and workplace concentrations provided by Formaldehyde manufacturers

Seventeen different companies provided data representing Formaldehyde worker exposure during manufacturing within Europe dated from 1993 till 2012. The total dataset consists of 143 personal long-term data, 67 personal short-term data, 178 stationary long-term data and 16 stationary short-term data.

Basic analysis

Basic analysis of personal long term worker measurements resulted in a 90^{th} percentile value of 0.32 mg/m^3 (N=143) which is below the reference value of 0.50 mg/m^3. The short term 95^{th} percentile value of 3.25 mg/m^3 (N=67) exceeds the reference value of 1.0 mg/m^3.
This result suggest that specific risk management measures are necessary only in case of Formaldehyde peak exposure events. However, this rough basic analysis does not give insight in the representativeness of the dataset for all worker exposure during Formaldehyde manufacturing. In order to ensure that the total dataset covers all worker tasks and circumstances relevant for Formaldehyde worker exposure during Formaldehyde manufacturing, process steps and related worker activities were analyzed and used to perform job group and determinants analysis within the personal dataset.

The 90^{th} percentile value of stationary long term measurements is 2.11 mg/m^3 (N=178). Basic analysis of short term stationary exposure values results in a 95^{th} percentile value of 0.12 mg/m^3 (N=16). Stationary long term values are high compared to personal long term values. Stationary measurements are taken at a fixed location. Generally, those measurements aim at source identification and are located near a potential source of exposure. Personal measurements aim at presenting actual exposure to a substance during a shift. This is a possible explanation for the difference in Formaldehyde concentrations between personal long term and stationary long term values. Stationary short term values are low compared to personal short term values. This suggests that these measurements do have a short duration, but do not represent Formaldehyde peak exposure events.

Formaldehyde producers did provide a robust set of personal worker exposure measurements. Those data were used for risk assessment as they reflect actual worker exposure during Formaldehyde manufacturing the best.

Formaldehyde manufacturing process and related worker exposure

Formaldehyde has been produced commercially since 1889 by catalytic oxidation of methanol. Currently, the two predominant production processes are a silver catalyst process and a metal oxide catalyst process (Bizzari, 2007, referenced in NTP, 2010).

Most industrial production of Formaldehyde is in the form of Formalin. Formalin is an aqueous solution of formaldehyde with small amounts of stabilizers such as methanol to prevent polymerization. In modern plants formaldehyde solutions with 30 to 60 % w/w of formaldehyde are produced. (NTP 2010 and information from the manufacturers)

Worker exposure tasks that may result in formaldehyde exposure include collecting product samples for analysis, maintenance and repair operations, filter replacement and filling trucks and barrels. The main factors that affect occupational exposures to formaldehyde include the condition of the piping and equipment, the presence and efficiency of fume hoods or local collection systems at the source of the emissions, and the efficiency of the general ventilation system (NTP 2010).

Exposure measurements representing Formaldehyde exposure during manufacturing are categorized into job groups based on the job descriptions and corresponding tasks/activities described in the contextual information provided by Formaldehyde manufacturers.

Formaldehyde worker exposure during control of Formaldehyde manufacturing process

The job group Process control represents Formaldehyde exposure of workers that control the process of Formaldehyde manufacturing and perform sampling activities. Job group analysis on long term data describing process control activities during Formaldehyde manufacturing results in a 90th percentile value of 0.23 mg/m^3 (N=94) which is below the long term reference value of 0.50 mg/m^3. The calculated 95thpercentile value of corresponding short term process control data is 3.01 mg/m^3 (N=39) which exceeds the short term reference value of 1.0 mg/m^3.

Short term process control activities are reported to be performed in an indoor locations in 23 out of 39 cases. An outdoor location is described in 16 out of 39 cases. Dispersion is the movement of a contaminant from a source throughout the work area, giving rise to varying spatial concentrations. The dispersion of contaminants outdoors is different from indoors because there are in most cases few boundaries to contain the pollutant in the vicinity of the worker. In addition, the strength of the wind will generally be higher than the turbulent airflows inside buildings. For these reasons we expect that the dispersion outdoors will be greater than indoors (Fransman *et al.*, 2013). Because of this and because of other reasons it can be expected that outdoor concentrations may be different from indoor concentrations. This effect is however not visible in this group of short term process control data.

Selection of data describing specific technical risk management measures (e.g. Closed system, LEV) did not result in a safe scenario for short term process control activities as well.

Respiratory protection with a protection factor of 10 (RPE PF10) reduce the actual exposure tenfold. Generally, prescription of RPE PF 10x (*e.g.* half masks) is considered acceptable as risk management measure to protect workers from Formaldehyde peak exposure events. The use of this risk management measure is confirmed by the contextual information of only 5 out of 39 short term process control data and therefore does not appear to be general practice at present. Hence, use of RPE PF 10x needs to be implemented as general risk management measure during short term exposure events as part of control of the Formaldehyde manufacturing process. Use of respiratory protection with a protection factor of 10 during short term process control activities results in a 95th percentile value of 0.30 mg/m^3 (N=39) which is below the reference value. The scenario is summarized Table 3.

Table 3. Worker exposure to formaldehyde in process control at manufacturing sites of formaldehyde

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Formaldehyde manufacturing	Process control & sampling Indoor/Outdoor 20-62% Formaldehyde	Closed system Dedicated sampling points	Personal Long-term (90th perc)	0.23 (N=94)
	Process control & sampling Indoor/Outdoor 37-60% Formaldehyde	Closed system + general ventilation/dedicated sampling points RPE PF 10x	Personal Short-term (95th perc)	0.30 (N=39)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during Maintenance & Cleaning of Formaldehyde manufacturing process

The job group Maintenance & Cleaning represents Formaldehyde exposure of workers that service, repair, clean and/or perform filter change as part of the Formaldehyde manufacturing process. Job group analysis on long term data describing maintenance/cleaning activities as part of Formaldehyde manufacturing results in a 90th percentile value of 0.22 mg/m^3 (N=25) which is below the long term reference value of 0.50 mg/m^3. The calculated 95thpercentile value of corresponding short term process control data is 5.88 mg/m^3 (N=10) which exceeds the short term reference value of 1.0 mg/m^3. However, use of respiratory protection is not taken into account in this value. Use of RPE is confirmed by contextual information of 9 out of 10 short term maintenance/cleaning measurements. Hence, RPE is considered to be a realistic risk management measure during these activities. Use of respiratory protection with a protection factor of 10 (e.g. half masks) results in a 90th percentile value of 0.59 mg/m^3 (N=10) which is below the reference value. The scenario is summarized in Table 4.

Table 4. Formaldehyde worker exposure during maintenance/cleaning of the manufacturing process

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Formaldehyde manufacturing	Service/Repairs/ Filter change/cleaning Indoor/Outdoor 40-55% Formaldehyde	Handling/Transfer in closed system Drain down/Flush prior opening	Personal Long-term (90th perc)	0.22 (N=25)
	Service/Repairs/ Filter change/cleaning Indoor/Outdoor 40-54% Formaldehyde	Handling/Transfer in closed system RPE PF 10x	Personal Short-term (95th perc)	0.59 (N=10)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during transfer of Formaldehyde and Resins

Separate groups of data representing transfer activities during manufacturing of Formaldehyde or resins were relatively small and did not support determinants analysis. Therefore, worker exposure data representing loading/unloading of Formalin and Formaldehyde based resins in tankers and rail cars are combined into one job group defined as liquid transfer. Combination of the data of both industries is justified by the similar worker activities, tasks, and Formaldehyde concentrations described by the contextual information. Job group analysis on long term data describing transfer activities results in a 90th percentile value of 0.47 mg/m^3 (N=49) which is just below the long term reference value of 0.50 mg/m^3. For 23 out of this 49 measurements, the use of a dedicated transfer system is confirmed by the contextual information (e.g. closed transfer provided with local exhaust ventilation, use of drybreak couplings, clearance of transfer lines before decoupling). Selection and analysis of these measurements results in 90th percentile value of 0.43 mg/m^3 (N=23). Taking the hazardous properties of Formaldehyde into account, the use of a dedicated system is considered good practice for transfer of Formaldehyde and Formaldehyde based resins. Hence, this scenario is presented in Table 5.

The calculated 95thpercentile value of corresponding short term transfer data is 2.62 mg/m^3 (N=15) which exceeds the short term reference value of 1.0 mg/m^3. However, use of respiratory protection is not taken into account in this value. Use of RPE is confirmed by contextual information of 7 out of 15 short term measurements and is considered to be a realistic risk management measure during short term transfer activities. Use of respiratory protection with a protection factor of 10 (e.g. half masks) results in a 95th percentile value of 0.26 mg/m^3 (N=15) which is below the reference value. The scenario is summarized in Table 5.

Table 5. Formaldehyde worker exposure during transfer of Formaldehyde and Resins

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Manufacturing of Formaldehyde and Resins	Loading/Unloading Indoor/Outdoor 2-55% Formaldehyde	Indoor; Closed filling + LEV Outdoor; Closed filling + LEV or clearing	Personal Long-term (90th perc)	0.43 (N=23)
	Loading/Unloading Indoor/Outdoor 0.8-55% Formaldehyde	Closed filling RPE PF 10x	Personal Short-term (95th perc)	0.26 (N=15)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins

Formaldehyde manufacturers provided a limited number of data representing Formaldehyde worker exposure during Laboratory use. It was decided to compose one job group representing Formaldehyde exposure of laboratory personnel within the Formaldehyde and Resin manufacturing industry. Combination of the data of both industries is justified by the similar worker activities, tasks, and Formaldehyde concentrations described by the contextual information. Laboratory use of Formaldehyde and Resins can be subdivided in 3 subgroups; laboratory workers using formaldehyde and/or resins for product analysis, plant operators performing laboratory activities for adjustment of formaldehyde concentrations in the storage tanks, research workers using formaldehyde and/or resins for product development and research (R&D) (Expert communication). The available contextual information does not support discrimination between Laboratory workers using formaldehyde and/or resins for product analysis and plant operators performing laboratory activities for adjustment of formaldehyde concentrations in the storage tanks. Hence, results are presented for two separate groups;

- Laboratory use for R&D work
- Laboratory use for product analysis of laboratory personnel and plant operators

The use of Formaldehyde and/or resins for R&D work is represented by 7 personal long term data ranging from 0.014 – 0.35 mg/m^3. There are three short term R&D data available with values from 0.005 – 3.13 mg/m^3. This result suggest that specific risk management measures are necessary in case of Formaldehyde peak exposure events during R&D work. However, the number of data is too small for conclusions.

Job group analysis on long term data describing laboratory use for product analysis results in a 90th percentile value of 0.25 mg/m^3 (N=70) which is below the long term reference value of 0.50 mg/m^3. The calculated 95thpercentile value of corresponding short term product analysis data is 1.18 mg/m^3 (N=12) which exceeds the short term reference value of 1.0 mg/m^3. The short term dataset representing product analysis data consist of 12 data points with corresponding measurement values from 0.0006 – 0.25 mg/m^3. The calculated GM and GSD values are 0.02 mg/m^3 and 11.51 respectively. The high variety in measured values results in a GSD value of 11.51. This GSD value is unusually high and indicates that the short term product analysis data do not form one homogenous group. In this case, the calculated 95th percentile value is considered an artifact caused by the very high GSD and is considered not representative for the real short term exposure during product analysis in a Laboratory setting. Hence, short term exposure during product analysis is estimated based on long term product analysis data. The estimated 95th percentile value of short term laboratory use for product analysis is 0.50 mg/m^{-3} which is below the short term reference value of 1.0 mg/m^3. The scenario is summarized in Table 6.

Table 6. Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Manufacturing of Formaldehyde and Resins	Laboratory work Product analytics Indoor 0.4 – 55%	General ventilation Fume cupboard Closed sampling	Personal Long-term (90th perc)	0.25 (N=70)
			Personal Short-term (95th perc)	0.50 (Estimation)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

4.2 Worker exposure data and workplace concentrations provided by Formaldehyde based resin / chemical producers

Twenty-one different companies provided data representing Formaldehyde worker exposure during manufacturing of Formaldehyde based resins or other chemicals (use as intermediate) within Europe dated from 1996 till 2012. The total dataset includes 759 personal long-term data, 102 personal short-term data, 162 stationary long-term data and 86 stationary short-term data.

Basic analysis

Basic analysis of personal long term worker measurements result in a 90th percentile value of 0.56 mg/m^3 (N=759) which is just above the reference value of 0.50 mg/m^3. The short term 95th percentile value of 3.51 mg/m^3 (N=102) exceeds the reference of 1.0 mg/m^3 as well.

This result suggest that specific risk management measures are necessary to ensure safe use during the Formaldehyde based resin / chemical production. However, this rough basic analysis does not give insight in the underlying worker activities and circumstances resulting in these exposure values. Additional job group and determinants analysis is used to refine worker exposure assessment for all specific worker activities and corresponding circumstances.

The 90th percentile value of stationary long term measurements is 0.54 mg/m^3 (N=162). Basic analysis of short term stationary exposure values results in a 95th percentile value of 0.20 mg/m^3 (N=86). Stationary long term values are similar to personal long term values. Stationary short term values are low compared to personal short term values. This suggests that these measurements do have a short duration, but do not represent Formaldehyde peak exposure events.

Producers of Formaldehyde based resins and other chemicals did provide a robust set of personal worker exposure measurements. Those data were used for further analysis and risk assessment as they reflect actual worker exposure during manufacturing of Formaldehyde based resins and other chemicals the best.

Formaldehyde based resin / chemicals manufacturing process and related worker exposure

The predominant industrial use of formaldehyde is in the manufacture of other chemicals (use as intermediate) and urea-, phenol-, and melamine-formaldehyde resins. Another major use is in the manufacturing of polyacetal resins.

Resin synthesis and production of other chemicals occurs by chemical reactions. For example, urea formaldehyde (UF) resins are produced by combining urea and formaldehyde heated with a mild acid catalyst like ammonia. Melamine formaldehyde (MF) resins are made from melamine and formaldehyde by polymerization. (http://www.formacare.org/index.php?page=applications)

Worker exposure tasks that may result in formaldehyde exposure during resin / chemicals production are similar to the tasks within the Formaldehyde manufacturing industry; collecting product samples for analysis, maintenance and repair operations, filter replacement, bagging, and filling trucks and barrels. Exposure values may however vary due to differences in Formaldehyde content of the Formulations and the physical state of the Formaldehyde based products. Besides the worker activities mentioned above, process control, cleaning & maintenance, liquid transfer and laboratory use, process operation and solid transfer activities are relevant for Formaldehyde worker exposure within the resin / chemicals manufacturing industry. The dataset provided by Formaldehyde based resin / chemicals manufacturers describes a substantial number of management activities as well. Those are analyzed and reported as separate group.

Formaldehyde worker exposure during control of Resin / chemicals manufacturing process

The job group Process control represents Formaldehyde exposure of workers that control the process of resin / chemicals manufacturing and perform sampling activities. Job group analysis on long term data describing process control activities during Formaldehyde based resin / chemicals manufacturing results in a 90^{th} percentile value of 0.37 mg/m^3 (N=116) which is below the long term reference value of 0.50 mg/m^3. The calculated 95^{th}percentile value of corresponding short term process control data is 1.62 mg/m^3 (N=43) which exceeds the short term reference value of 1.0 mg/m^3.

Amongst the group of 43 short term process control data, there are 17 measurements provided by 3 companies describing closed handling and sampling of Formaldehyde based resin / chemicals during process control. Determinants analysis of this subgroup results in a 95^{th} percentile value of 0.64 mg/m^3 (N=17) which is below the short term reference value. Despite the limited number of companies that confirmed the use of a closed handling and sampling system during short term process control activities, this scenario is considered good practice to prevent Formaldehyde peak exposure events. Hence, this scenario is described in Table 7.

Table 7. Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Resin / chemicals manufacturing	Process control & sampling Indoor/Outdoor 0.4-85 % Formaldehyde	Closed system LEV	Personal Long-term (90th perc)	0.37 (N=116)
	Process control & sampling Indoor/Outdoor 20-55% Formaldehyde	Closed handling and sampling	Personal Short-term (95th perc)	0.64 (N=17)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during operation of Resin / chemicals manufacturing process

The job group Process operation represents Formaldehyde exposure of workers that operate resin / chemicals production reactors, charge raw materials and perform spray drying activities. Job group analysis on long term data describing process operation activities during Formaldehyde based resin / chemicals manufacturing results in a 90th percentile value of 0.73 mg/m^3 (N=348) which exceeds the long term reference value of 0.50 mg/m^3. Determinants analysis on 95 long term process operation data describing the use of a closed system and LEV results in a 90th percentile value of 0.25 mg/m^3 which is below the reference value of 0.50 mg/m^3. Hence, safe use of Formaldehyde during long term process operation activities is demonstrated assuming the use of a closed system and LEV. This scenario is described in Table 8. The calculated 95thpercentile value of corresponding short term process operation data is 1.97 mg/m^3 (N=29) which also exceeds the short term reference value of 1.0 mg/m^3. However, use of respiratory protection is not taken into account in this value. Use of RPE is confirmed by contextual information of 20 out of 29 short term process operation measurements. Hence, RPE is considered to be a realistic risk management measure during short term process operation activities. Use of respiratory protection with a protection factor of 10 (*e.g.* half masks) results in a 95th percentile value of 0.20 mg/m^3 (N=29) which is below the reference value. The scenario is summarized in Table 8.

Table 8. Formaldehyde worker exposure during control of the Resin / chemicals manufacturing process

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m³ (N)[1]
Resin / chemicals manufacturing	Resin / chemicals production reactor operation, charging raw materials, spray drying Indoor/Outdoor 0 – 96% Formaldehyde	Closed system LEV	Personal Long-term (90th perc)	0.25 (N=95)
	Resin / chemicals production reactor operation, charging raw materials, spray drying Indoor/Outdoor 0.5 – 60% Formaldehyde	Mechanical/Natural ventilation RPE PF 10x	Personal Short-term (95th perc)	0.20 (N=29)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during management of the Resin / chemicals manufacturing process

The job group management represents Formaldehyde exposure of workers that are responsible for production management mainly consisting of office work. The dataset provided by resin and other chemical manufacturers includes 73 personal long term measurements categorized in the job group management. The dataset does not include short term management data. As management activities do have a low potential of peak exposure values and any peak exposure values are expected to be purely by coincidence, job group analysis is restricted to the long term exposure route. Job group analysis on long term data describing management activities during Formaldehyde based resin / chemicals manufacturing results in a 90^{th} percentile value of 0.31 mg/m^3 (N=73) which is below the long term reference value of 0.50 mg/m^3. The scenario is described in Table 9.

Table 9. Formaldehyde worker exposure during management as part of Resin / chemicals manufacturing process

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m³ (N)[1]
Resin / chemicals manufacturing	Office work and production management Indoor/Outdoor 30-96% Formaldehyde	General ventilation	Personal Long-term (90th perc)	0.31 (N=73)
			Personal Short-term (95th perc)	Not relevant

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during Maintenance & Cleaning of Resin / chemicals manufacturing process

The job group Maintenance & Cleaning represents Formaldehyde exposure of workers that service, repair, clean and/or perform filter change activities as part of the resin / chemicals manufacturing process. Job group analysis on long term data describing maintenance/cleaning activities results in a 90^{th} percentile value of 1.18 mg/m^3 (N=68) which exceeds long term reference value of 0.50 mg/m^3. Available short term measurements representing cleaning and maintenance activities range from 0.0061-12.28 mg/m^3 (N=9). The data show that cleaning & maintenance activities during the resin / chemicals manufacturing process do have a high potential for Formaldehyde worker exposure.

Selection of data describing specific risk management measures (e.g. LEV, flushing the system before maintenance/cleaning activities) did not result in the description of a safe scenario for long term maintenance and cleaning activities. Subdivision of the data into subgroups describing maintenance and cleaning activities separately does not result in a safe scenario as well. Generally, the use of RPE is not considered a very feasible risk management measure in case of long term worker activities. The use of RPE is however confirmed by 27 out of the 68 long term maintenance & cleaning activities. This indicates that the use of RPE is not unusual in specific maintenance & cleaning activities. Use of respiratory protection with a protection factor of 10 (e.g. half masks) results in a 90^{th} percentile value of 0.12 mg/m^3 (N=68) which is below the reference value.

As limited number of 9 short term data on cleaning and maintenance activities are available in the dataset, the 95^{th} percentile short term exposure value is estimated on the long term data resulting in a value of 2.35 mg/m^3. Use of RPE is described for 7 out of 9 short term cleaning & maintenance data. In line with the long term data on maintenance and cleaning, use of half masks need to be assumed to ensure safe use for short term Formaldehyde exposure. The estimated short term 95^{th} percentile value for maintenance/cleaning corrected for RPE PF 10 is 0.24. The scenario is summarized in Table 10.

Table 10. Formaldehyde worker exposure during maintenance/cleaning of the resin / chemicals manufacturing process

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Resin / chemicals manufacturing	Service/Repairs/ Filter change/cleaning Indoor/Outdoor 0 - 96% Formaldehyde	Drain down/Flush prior opening and/or LEV RPE PF 10x	Personal Long-term (90^{th} perc)	0.12 (N=68)
			Personal Short-term (95^{th} perc)	0.24 (Estimation)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during transfer of solid Resins

The dataset provided by manufacturers of Formaldehyde based resins includes 44 personal long term measurements representing Formaldehyde worker exposure during Bagging and/or filling of solid resin. The calculated 90th percentile value is 0.29 mg/m^3 (N=44) which is below the long term reference value of 0.50 mg/m^3. There are 4 data available representing short term worker exposure during solid transfer activities ranging from 0.09 – 2.09 mg/m^3. Due to a limited number of 4 short term data on solid transfer in the dataset, the 95th percentile short term exposure value is estimated based on the long term data resulting in a value of 0.58 mg/m^3. This value is below the short term reference value of 1.0 mg/m^3. The scenario is described in Table 11.

Table 11. Formaldehyde worker exposure during transfer of solid resin

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Resin / chemicals manufacturing	Bagging/Filling solid resin Indoor/Outdoor 0-96% Formaldehyde	Closed system + LEV	Personal Long-term (90th perc)	0.29 (N=44)
			Personal Short-term (95th perc)	0.58 (Estimation)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during transfer of liquid Formaldehyde and Resins / chemicals

Formaldehyde worker exposure during transfer of liquid Formaldehyde and resins / chemicals is described in chapter "*Worker exposure data and workplace concentrations provided by Formaldehyde manufacturers*"

Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins / chemicals

Formaldehyde worker exposure during Laboratory use of Formaldehyde and Resins / chemicals is described in *"Worker exposure data and workplace concentrations provided by Formaldehyde manufacturers"*

4.3 Worker exposure data and workplace concentrations provided by wood panel producers

Twenty-eight different companies provided data representing Formaldehyde worker exposure in the European wood panel industry from 1996 till 2003. Worker exposure measurements from the European so-called 'Ref-wood' study, reported by Acton (2009) were taken into account as well. The total dataset includes 246 personal long-term data, 222 personal short-term data, 219 stationary long-term data and 246 stationary short-term data. The dataset provided by wood panel producers represent Formaldehyde worker exposure values during the production of medium density fiberboard (MDF), high density fiberboard (HDF), Melamine Faced Chipboard (MFC), particleboard (PB), Chipboard and Plywood panels using a single-stage, multi-stage or continuous process. Formaldehyde based resins used for panel production and/or impregnation of paper for lamination include urea-formaldehyde resin, melamine-formaldehyde resin, melamine-urea-formaldehyde resin, melamine-urea-phenolic-formaldehyde resin and phenolic-formaldehyde resin.

Basic analysis

Basic analysis of personal long term and stationary long term measurements result in a 90th percentile values of 0.54 mg/m^3 (N=246) and 1.06 mg/m^3 (N=219) respectively.

Basic analysis results of personal and stationary long term values are above the reference value of 0.50 mg/m^3. Stationary long term values are high compared to personal long term values. Stationary measurements are taken at one fixed location. Generally, those measurements aim at source identification and are located near to a potential source of exposure. Personal measurements aim at presenting actual exposure to a substance during a shift. Generally, panel production workers make use of a control room separate from the process area for part of their activities. The location of the stationary measurements close to sources and the absence of the protecting effect from a control room are possible explanations for the difference in Formaldehyde concentrations between personal long term and stationary long term values.

The 95th percentile values of personal short term and stationary short term measurements are 0.93 mg/m^3 (N=222) and 0.88 mg/m^3 (N=246) respectively. Basic analysis results in similar 95th percentile values for personal and stationary short term measurements just below the reference value of 1.0 mg/m^3. This result suggest that job group analysis of short term exposure measurements results in exposure values above the reference value for some job groups and below the reference value for other job groups depending on the specific work activities. Both personal and stationairy short term values are low compared to the long term values. This suggests that these measurements do have a short duration, but do not represent Formaldehyde peak exposure events.

Wood panel production process and related Formaldehyde worker exposure

The wood panel production process includes pre-press, press and after-press operations.

The pre-press area is located outdoors and includes wood storage, wood preparation, screening/sifting and drying of wood particles. Press operations are located indoors and include Glue preparation (glue kitchen), gluing, mat forming of wood particles and subsequent prepress, press and star cooler operations. Generally, the glue kitchen, gluing, mat forming, prepress, press, and star cooler form one unity in the indoor press hall. The after-press area is located indoors as well and includes separate sanding/sawing, impregnation, lamination, packaging and storage areas. Analytical activities are performed in a separate laboratory building (Expert communication).

As this study focusses on Formaldehyde worker exposure due to handling of Formaldehyde based products, Formaldehyde worker exposure during wood storage, wood preparation and screening/sifting in the pre-press area are outside of the scope of this study.

Formaldehyde based resins are introduced in the process during the gluing step. Gluing takes place just before or after drying of the wood particles depending on the type of wood panel product (e.g. gluing before drying during MDF production, gluing after drying during Particleboard/OSB production). Drying of the wood particles is a separate process outside and apart from the press area. Dryer operators are generally working in the pre-press area controlling the process of drying. Dryer operators and (press) process operators can however share the same control room (Expert communication). The dataset provided by wood panel producers contains two personal long term Formaldehyde values of dryer operators (0.04 and 0.14 mg/m^3). Two personal short term values are available with values of 0.005 and 0.12 mg/m^3 respectively. The available values suggest that drying activities do not have a high Formaldehyde exposure potential.

Workers in the wood panel production industry can be subdivided in “fixed location workers” and “mobile workers”. Fixed location workers are workers whose jobs keep them primarily in a specific section of the wood panel production process. Hence, Formaldehyde exposure of fixed location workers can be related to the process area in combination with the specific worker activities. Mobile workers move among the different areas of the wood panel production process. Their exposure cannot be related to a specific process area. Formaldehyde exposure of mobile workers is the result of their specific worker activities in combination with exposure determinants in their variable location. Depending on the process area and the specific activities of the workers, Formaldehyde sources within the wood panel industry include liquid non-polymerised Formaldehyde based resin and/or Formaldehyde emissions from solid wood panels and dust.

Exposure measurements representing Formaldehyde exposure in the wood panel industry are categorized into job groups based on a combination of their tasks/activities and working areas. Specific expert communication and job descriptions provided by the wood panel industry are taken into account in composing, describing and analyzing the job groups.

Formaldehyde worker exposure during Panel production operation

The job group ‘Panel production operation’ represents Formaldehyde exposure of fixed location workers whose jobs keeps them primarily in the press area of the wood panel production process. Those operators are responsible for the process steps gluing, forming, pressing and cooling. The job group panel production operation includes a limited number of mobile workers whose Formaldehyde exposure is considered to be mainly caused by activities in the press area. Those workers fulfill a function of shift leader or production manager performing inspection rounds. Drying operators performing QC inspections in the press area as part of their job are categorized in the job group Panel production operation as well. Panel production workers generally make use of a control room for part of their activities. The main Formaldehyde source of Panel production workers is not yet fully polymerised Formaldehyde based resin that is used as glue in the process.

Job group analysis on Long term panel production data results in a 90th percentile value of 0.75 mg/m^3 (N=81) which is above the long term reference value of 0.50 mg/m^3. The calculated 95thpercentile value of corresponding short term panel production measurement data is 0.93 mg/m^3 (N=31). The 95th percentile short term exposure value estimated on the long term dataset is 1.51 mg/m^3. Compared to the short term reference value of 1.0 mg/m3, estimation of short term values from the long term measurement data results in values above the reference, available data are just below this reference. The 95th percentile short term value of short term panel production data is relatively low. This can be caused by short term measurements not being aimed at high exposure activities, but simply being measurements of general exposure during a short time. To prevent possible underestimation of short term values, the estimated 95th percentile value of short term panel production measurements (1.51 mg/m^3) is taken forward to the risk assessment.

Use of a control room for part of the panel production activities is confirmed by the contextual information of 57 out of 81 long term panel production measurements. Use of a control room for all panel production activities (full shift) is confirmed by contextual information of only 1 data point. Contextual information of 4 of the 81 long term panel production measurements states that a control room is not used during the activities. In 19 cases, the contextual information does not include any information on use of a control room during the panel production activities. As use of a control room for part of the panel production activities is confirmed in 57 out of 81 cases and not specifically reported (either to confirm or to indicate that there is no use) for 19 out of 81 cases , it is concluded that use of a control room is general practice for part of the activity. This is also confirmed by several industry representatives contacted during this study.

Analysis of long term panel production data in cases where workers used the control room for more than 50% of the measurement duration results a 90th percentile value of 0.76mg/m^3 (N=38). This value is low compared to 90th percentile value of personal long term panel production data in cases where workers used the control room for less than 50% of the measurement duration; 1.65 mg/m^3 (N=12). This result indicates a protecting effect of a control room regarding Formaldehyde worker exposure.

To investigate the protecting effect of using a control room during panel production activities, specific measurements representing Formaldehyde concentrations in control rooms were gathered. This dataset consist of 3 personal long term panel production data in which all worker activities were performed from the control room. Additionally, formaldehyde concentrations in control rooms measured by 14 stationary long term measurements were provided. Those stationary measurements are considered representative for personal panel production worker exposure if workers perform all activities from a control room. This can be explained by the fact that worker activities in the control room are performed in one fixed location and Formaldehyde exposure due to other workers or processes is not expected. Concentrations within a control room are also considered to be not location specific, due to the lack of sources in the control room. The 90th percentile value of these control room values is 0.26 mg/m^3 (N=17) which is below the reference value of 0.50 mg/m^3.

There are 49 stationary long term measurements available representing Formaldehyde concentrations in the press area. The corresponding 90th percentile value is 2.36 mg/m^3 (N=49). This information indicates Formaldehyde worker exposure above the reference value in case of activities in the press area, and below the reference value during activities performed in a control room. Specific contextual information on these data points is limited. According to industry experts, the stationary sampling is specifically done at locations close to where emission of formaldehyde is expected, such as the outlet of the press. It is therefore very well possible that concentrations are much lower further away from emission points.

Use of respiratory protection is confirmed by contextual information of 49 out of 81 long term panel production measurements. The short term panel production data describe use of RPE in 20 out of 31 cases. Hence, RPE seems to be a realistic risk management measure during (at least part of the) panel production activities. The 90th percentile value of personal long term panel production measurements is 0.75 mg/m^3 (N=81) without correction for use of RPE. Use of respiratory protection with a protection factor of 10 (e.g. half masks) results in a 90th percentile value of 0.075 mg/m^3 which is below the reference value. However, the protecting effect of use of a control room is included in the personal long term values, because at least 57 out of 81 measurements were on workers performing part of their activities in a control room. The 90th percentile value of long term stationary measurements in the press area is 2.36 mg/m^3 (N=49) which is considered a worst case Formaldehyde concentration without inclusion of the protecting effect of a control room and/or respiratory protection. Use of respiratory protection with a protection factor of 10 is sufficient to reduce the Formaldehyde concentration below the reference value as well.

The 95th percentile short term exposure value estimated on the long term dataset is 1.51 mg/m^3. This value is used for risk assessment. Use of respiratory protection with a protection factor of 10 is sufficient to reduce the short term Formaldehyde exposure to 0.15 mg/m^3 which is below the reference value of 1.0 mg/m^3.

It is considered that the combination of all this information underpins a safe scenario for panel production activities in which respiratory protection with a protection factor of 10 (*e.g*. half masks) is used during panel production activities in the press area, *i.e.* outside of the control room. This is specifically needed when working close to emission points (where it is expected that most of the static samples have been taken) and may not be necessary in other areas outside of the control room. Because of the variation in set-up of the installations it is up to each company to define in what specific areas use of respiratory protection is needed outside of the control room. Use of respiratory protection is not necessary during panel production activities performed in a control room. This scenario is summarized in Table 12.

Table 12. Formaldehyde worker exposure during production of wood based panels

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)
Panel production	Operation of gluing, forming, pressing and cooling process Indoor 0.008 -8% Formaldehyde	No/Partial enclosure Part of work in control room General ventilation (Natural and/or mechanical) LEV Use of RPE PF 10x[a)]	Personal Long-term (90th perc)	0.075 (N=81)
			Personal Short-term (95th perc)	0.15 (Estimation)

[a)] The use of RPE is specifically needed when working close to emission points and may not be needed elsewhere outside of the control room. Each company needs to define where the use of RPE is needed.

Formaldehyde worker exposure during impregnation and lamination of panel boards

The job group Impregnation represents Formaldehyde worker exposure of fixed location workers whose job keeps them primarily in the impregnation area. Impregnation operators impregnate paper using Formaldehyde based resins with resin baths and dryers. These workers normally do not make use of a control room. The main Formaldehyde source of Impregnation workers is non-polymerized Formaldehyde based resin.

Job group analysis on long term impregnation data results in a 90th percentile value of 0.40 mg/m^3 (N=17) which is below the long term reference value of 0.50 mg/m^3. The calculated 95thpercentile value of corresponding short term impregnation data is 0.53 mg/m^3 (N=56). The 95th percentile short term exposure value estimated on the long term dataset is 0.79 mg/m^3. Short term impregnation values appear to be low compared to long term values. To prevent the possible underestimation of short term exposure estimates based on measured data, the calculated 95th percentile value for short term impregnation (0.79 mg/m^3) is used for risk assessment. For the impregnation process, personal long term and short term exposure values are below the reference values of 0.50 and 1.0 mg/m^3 respectively. Hence, safe use of Formaldehyde based resins during impregnation is demonstrated by available data and circumstances described in Table 13.

The job group Lamination represents Formaldehyde worker exposure of fixed location workers whose job keeps them primarily in the lamination area. Lamination operators use impregnated paper to laminate panel boards. Their primary task is controlling the laminating press. Usually, these workers do not make use of a control room. The main Formaldehyde source of Lamination workers are Formaldehyde emissions from impregnated paper and solid wood panels.

Job group analysis on long term lamination data results in a 90th percentile value of 0.15 mg/m^3 (N=30) which is below the long term reference value of 0.50 mg/m^3. The calculated 95thpercentile value of short term lamination data is 0.40 mg/m^3 (N=49). Available data demonstrate safe use for Formaldehyde based products during lamination activities as part of the wood panel production process. The scenario is summarized in Table 13.

Table 13. Formaldehyde worker exposure during paper impregnation and lamination of wood based panels

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Panel production	Paper impregnation Indoor <0.2 – 1.5% Formaldehyde	Partial enclosure General ventilation (Natural and mechanical) LEV	Personal Long-term (90^{th} perc)	0.40 (N=17)
			Personal Short-term (95^{th} perc)	0.79 (Estimation)
	Paper lamination Indoor <0.1 – 1% Formaldehyde	No/Partial enclosure General ventilation (Natural and/or mechanical) LEV	Personal Long-term (90^{th} perc)	0.15 (N=30)
	Paper lamination Indoor 0.1 – 1% Formaldehyde	General ventilation (Natural and/or mechanical) LEV	Personal Short-term (95^{th} perc)	0.40 (N=49)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during sanding & sawing of panel boards

The job group Sanding & Sawing represents Formaldehyde worker exposure of fixed location workers whose job keeps them primarily at the sanding line. Generally, sanding operators control the sanding process from a control room and regularly perform inspections in the sanding area. The main Formaldehyde source of Sanding & Sawing workers are Formaldehyde emissions from solid wood panels and dust.

Job group analysis on long term sanding & sawing data results in a 90^{th} percentile value of 0.33 mg/m^3 (N=33) which is below the long term reference value of 0.50 mg/m^3. The 95^{th}percentile value of short term sanding & sawing data is 1.15 mg/m^3 (N=15). Available data demonstrate safe use for long term sanding & sawing of wood panels. Short term exposure values appear to be above the reference value of 1.0 mg/m^3. However, use of respiratory protection is not taken into account in this value. Use of RPE is confirmed by contextual information of 11 out of 15 short term sanding & sawing measurements. Hence, RPE is considered to be a realistic risk management measure during short term sanding & sawing activities. Use of respiratory protection with a protection factor of 10 (e.g. half masks) results in a 90^{th} percentile value of 0.12 mg/m^3 which is below the reference value. The scenario is summarized in Table 14.

Table 14. Formaldehyde worker exposure during sanding & sawing of wood based panels

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Panel production	Operation of sanding&sawing line Indoor 0.008 -1% Formaldehyde	No/Partial enclosure No/part of work in control room General ventilation (Natural and/or mechanical) +/-LEV	Personal Long-term (90^{th} perc)	0.33 (N=33)
	Operation of sanding&sawing line Indoor 0.004 -1% Formaldehyde	General ventilation (Natural and/or mechanical) +/-LEV Use of RPE PF 10x	Personal Long-term (90^{th} perc)	0.12 (N=15)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during cleaning and maintenance activities in the wood panel industry

The job group Maintenance represents mobile location workers that perform maintenance activities in different areas of the panel production process. Specific activities include intervention at devices that do not function properly. Whether panel production and maintenance activities take place simultaneously depends on the device that needs to be maintained. The Formaldehyde source of maintenance workers depends on the specific maintenance tasks and area of the production process.

The dataset provided by wood panel producers includes 24 personal long term data representing worker exposure during maintenance activities. The 90^{th} percentile value of these data is 0.43 mg/m^3 (N=24) which is below the reference value of 0.50 mg/m^3. As short term data on maintenance activities are not available in the dataset, the 95^{th} percentile short term exposure value is estimated based on the long term dataset resulting in a value of 0.86 mg/m^3. Available data demonstrate safe use for maintenance activities. The scenario is summarized in Table 15.

The job group Cleaning represents mobile location workers that perform cleaning, degreasing, blowing and sweeping activities in different areas of the panel production process. Generally, cleaning workers make use of personal protective equipment. Usually, cleaning activities and wood panel production are performed simultaneously. The Formaldehyde source of cleaning workers depends on the specific cleaning tasks and area of the production process.

The dataset provided by wood panel producers includes 18 personal long term data representing worker exposure during cleaning activities. The 90^{th} percentile value of these data is 1.99 mg/m^3. The calculated 95^{th}percentile value of corresponding short term cleaning measurement data is 1.89 mg/m^3 (N=34). The 95^{th} percentile short term exposure cleaning value estimated on the long term dataset is 3.98 mg/m^3. Short term cleaning values appear to be low compared to long term values. To prevent the possible use of underestimation of short term values from measured data that may not sufficiently represent high exposure activities, the calculated 95th percentile value for short term cleaning based on long term exposure measurements (3.98 mg/m^3) is used for risk assessment.

Both long term and short term cleaning data appear to be above the reference values for Formaldehyde worker exposure. However, use of respiratory protection is not taken into account in this analysis. Use of RPE is confirmed by contextual information of 10 out of 18 long term and 27 out of 34 short term cleaning measurements. Hence, RPE is considered to be a realistic risk management measure during cleaning activities. Use of respiratory protection with a protection factor of 10 (*e.g.* half masks) result in a 90th percentile value of 0.20 mg/m^3 for long term cleaning activities and a 95th percentile value of 0.40 mg/m^3 for short term cleaning activities. These values are below the reference values for long term and short term worker exposure. The scenario is described in Table 15.

Table 15. Formaldehyde worker exposure during maintenance & cleaning in the wood panel industry

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Panel production	Maintenance/Intervention of devices Indoor 0.008 – 1% Formaldehyde	No/Partial enclosure No/part of work in control room General ventilation (Natural and mechanical) +/-LEV	Personal Long-term (90th perc)	0.43 (N=24)
			Personal Short-term (95th perc)	0.86 (Estimation)
	Cleaning (e.g. degreasing, blowing, sweeping) Indoor 0.1 – 1% Formaldehyde	No/part of work in control room General ventilation (Natural and/or mechanical) LEV RPE PF 10x	Personal Long-term (90th perc)	0.20 (N=18)
			Personal Short-term (95th perc)	0.40 (Estimation)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure during logistics in the wood panel industry

The job group Logistics represents Formaldehyde worker exposure of fixed location workers whose job keeps them primarily in the packaging area. Those workers sort, transport and pack the final wood panels. The main Formaldehyde source of Logistic workers are Formaldehyde emissions from solid wood panels.

Job group analysis on long term logistics data results in a 90th percentile value of 0.29 mg/m^3 (N=19) which is below the long term reference value of 0.50 mg/m^3. The 95thpercentile value of short term logistics data is 0.70 mg/m^3 (N=33). During sorting and packing of final board products, personal long term and short term exposure values are below the reference values of 0.50 and 1.0 mg/m^3 respectively. Hence, safe use during logistics is demonstrated by available data and circumstances described in Table 16.

The job group Laboratory represents Formaldehyde worker exposure of fixed location workers whose job keeps them primarily in the laboratory area. Those workers perform physical/chemical testing of final wood panels. Formaldehyde source of Laboratory workers can be both Formaldehyde emissions from solid wood panels and non-polymerized Formaldehyde based resin.

The dataset provided by wood panel producers includes 12 personal long term data representing worker exposure during laboratory activities. The 90th percentile value of these data is 0.30 mg/m^3 (N=12) which is below the reference value of 0.50 mg/m^3. The measurement value of the 2 short term laboratory data is 0.27 mg/m^3. Due to a lack of short term data on laboratory activities, the 95th percentile short term exposure value is estimated on the long term dataset resulting in a value of 0.60 mg/m^3. Available data demonstrate safe use for laboratory activities under the circumstances described by the data. The scenario is summarized in Table 16.

Table 16. Formaldehyde worker exposure during logistics & laboratory activities in the wood panel industry

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Panel production	Sorting/Packing panels Indoor 0.008 – 1% Formaldehyde	General ventilation (Natural and mechanical) LEV	Personal Long-term (90th perc)	0.29 (N=19)
	Sorting/Packing panels Indoor 0.004 – 1% Formaldehyde	General ventilation (Natural and mechanical) LEV	Personal Short-term (95th perc)	0.70 (N=33)
	Physical/Chemical testing Indoor 0.008 – 1% Formaldehyde	General ventilation (Natural and/or mechanical) LEV	Personal Long-term (90th perc)	0.30 (N=12)
			Personal Short-term (95th perc)	0.60 (Estimation)

1) The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

4.4 Worker exposure data and workplace concentrations provided by other downstream users

No data were received representing the following downstream uses:

- production of paper;
- production of bonded particulates;
- use of resins in wood applications (e.g. glues) and
- application of adhesives and coatings
- textile impregnation.

Data received from other downstream users are described in the following sections.

Formaldehyde worker exposure data and concentrations during formulation

Four different companies provided data representing Formaldehyde worker exposure during formulation of Formaldehyde based products in coatings, inks and nail hardeners. The dataset includes 13 personal long term data, 15 personal short term data, 10 stationary long term data and 9 stationary short term data measured between 2009 and 2012.

Analysis of personal long term worker measurements result in a 90th percentile value of 0.11 mg/m^3 (N=13) which is below the reference value of 0.50 mg/m^3. The 95th percentile value of short term data is 0.10 mg/m^3 (N=15). The 95th percentile short term exposure value is low compared to the 90th percentile long term value. To prevent the possible underestimation of short term values from short term measurements that may not have been sufficiently aimed at high exposure activities, the 95th percentile short term value is estimated by multiplying the 90th percentile long term value with a factor 2 (REACH Guidance R14). Estimation of the 95th percentile short term value on the long term formulation data results in a value of 0.23 mg/m^3. The estimation is conservative, compared to the measured short term exposure levels and therefore considered to be reasonable. Short term values are below the reference value of 1.0 mg/m^3 as well.

The 90th percentile value of stationary long term measurements is 0.18 mg/m^3 (N=10). Short term stationary exposure values range from 0.027 – 0.14 (N=9). Results of stationary long term values are somewhat higher than personal long term values. Stationary measurements indicate Formaldehyde workplace concentrations in formulation areas below the reference value.

Personal long term data represent weighing, loading, mixing and filling activities using products with a Formaldehyde content between 0.1-50%. Although the number of personal long term exposure values is limited, data are considered representative for worker exposure in European formulation industry as activities and formaldehyde content are representative for what is expected in the formulation of products with formaldehyde. Also, the fact that the data come from four different companies in three sectors suggests a reasonable spread over relevant product types. Table 17 presents the analyzed results of personal worker exposure data provided by Formulators. Those data are used for risk assessment.

Table 17. Formaldehyde exposure levels provided by Formulators of Formaldehyde based products

Use	Scenario	Technical Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Formulation	Weighing-Loading -Mixing-Filling Indoor 0.1-50% Formaldehyde	General ventilation (Natural and mechanical) LEV	Personal Long-term (90th perc)	0.11 (N=13)
			Personal Short-term (95th perc)	0.23 (Estimation)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure data and concentrations during Fertiliser granules production

Three different companies provided data representing use of urea formaldehyde (UF) resin for production of fertiliser granules. The dataset includes 1 personal long term data point, 8 personal short term data, and 1 stationary short term data point measured in 2011 and 2012.

Fertiliser granules are produced in an urea melt; a closed piping system controlled by an operator. The UF resin is transferred by closed dosing pumps to the urea melt. Operator activities are mainly performed from the control room. Activities outside the control room include sampling , cleaning and maintenance activities. The final solid Fertiliser granules are packaged and stored (Expert communication).

Formaldehyde exposure is mainly expected during coupling/decoupling of transfer hoses, sampling, cleaning and maintenance activities. As the formaldehyde content is low in the final end product, formaldehyde exposure is expected to be low during bagging and storage of end product. The personal long term data point represents Formaldehyde exposure of an operator during process control including sampling activities using UF resin with a Formaldehyde content of 4.5%. The corresponding measurement value is 0.15 mg/m^3 (N=1).

Tasks and activities within the personal short term data include transfer of UF resin and final Fertiliser granules. Besides that, both general operation activities and cleaning/maintenance activities are represented. The variety in activities does not result in differences in measured values; all values are below the detection limit of 0.2 ppm (= < 0.25 mg/m^3; N=8). The short measurement duration of 1.5 min is a possible reason for a lack in variety in measured concentrations. Although the activities in the personal short-term data are representative for the industry, the data is not sufficient as basis for risk assessment as the number of values is too limited, all data are provided by one company and Formaldehyde content is not known for 6 out of 8 samples.

The stationary short term data point represents Formaldehyde air concentrations in a workplace during cleaning activities using UF resin with a Formaldehyde content of 3% with general ventilation and LEV present. The corresponding measurement value of 0.27 mg/m^3 is high compared to the measured personal values.

Available data are considered insufficient as basis for risk assessment. Hence, worker exposure assessment is based on literature or modeled exposure values. Available data on Fertilizer granules production are presented in Table 18.

Table 18. Formaldehyde exposure levels provided by producers of Fertilizer granules

Use	Scenario	Technical Risk Management Measures	Type (unit)	Exposure value mg/m³ (N)[1]
Fertilizer granules production	Process control including; sampling Indoor 4.5% Formaldehyde	General ventilation (Natural and mechanical) Enclosed transfer Time duration max 4 hours	Personal Long-term (raw value)	0.15 (N=1)
	General operation, transfer, cleaning/maintenance Indoor/Outdoor 59% Formaldehyde	Natural ventilation	Personal Short-term (raw value)[2]	< 0.25 (N=8)
	Cleaning Indoor 3% Formaldehyde	General ventilation (Mechanical) LEV	Stationary Short-term (raw value)	0.27 (N=1)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure data and concentrations during Tyre and Rubber production

The European Tyre and Rubber Manufacturers Association provided one large dataset representing Formaldehyde worker exposure in 13 different Rubber and Tyre manufacturing plants. One other company provided Formaldehyde worker exposure data representing Formaldehyde worker exposure in the Rubber and Tyre industry. The total dataset includes 453 personal long-term data, 44 personal short-term data, 51 stationary short-term data and 3 stationary short-term data and represents Formaldehyde worker exposure in the Rubber and Tyre industry from 2004 till 2012.

Basic analysis

Basic analysis of personal long term and stationary long term measurements result in similar 90th percentile values of 0.05 mg/m^3 (N=453) and 0.04 mg/m^3 (N=44) respectively. The 95th percentile value of personal short term data is 0.06 mg/m^3 (N=51). Formaldehyde concentrations of three available stationary short term data range from 0.012 to 0.16 mg/m^3.
Basic analysis result in worker exposure values below the long term and short term reference values of 0.50 mg/m^3 and 1.0 mg/m^3 respectively. This result indicates safe use of Formaldehyde based products in the Rubber & Tyre industry. However, this rough basic analysis does not give insight in the underlying worker activities and circumstances resulting in these exposure values. Additional job group analysis is performed to ensure that the data represent all worker activities relevant for Formaldehyde worker exposure in the Rubber & Tyre industry.

Tyre & Rubber manufacturing process and related Formaldehyde worker exposure

Formaldehyde based resins fulfill a function as tackifier in the Tyre and rubber production process. The European Tyre and Rubber Manufacturers Association (ETRMA) distinguishes between Tyre production and production of other Rubber products. Basic process steps are however similar and include storage, weighing and loading of raw materials to the mixing chamber. After mixing, compounds are given a specific shape during the process of shaping consisting of calendaring and extrusion steps. During subsequent curing, most of the substances react into a three dimensional polymer network. In the final treatment, the Tyre/Rubber products are subjected to further treatment to enhance their appearance or make them part of a multi-component article. In both the production of Tyres and Rubber products, cement preparation is an optional process step. During this step, certain compounds are dissolved resulting in a liquid “cement” mixture used as glue between rubber components. Tyre products may be subjected to a retreading step. Retreading is an operation performed on second hand tyres including replacement of the old tyre tread with a new one. Retreading is not considered relevant for Formaldehyde worker exposure (Expert communication). As this study focusses on Formaldehyde worker exposure due to handling of Formaldehyde based products, retreading is outside of the scope of this study.

Potential worker exposure to pure Formaldehyde based resins can be expected during storage, weighing and loading of raw materials to the mixing chamber. The General exposure scenario (GES) on Rubber Goods and Tyres describes a concentration of Formaldehyde based resin up to 8% for Tyre production and 2% for other Rubber products during subsequent process steps. The Formaldehyde content described in the scenarios of table 19 till 23 are retrieved from the user data provided by the rubber industry. (General exposure scenario (GES) - General Rubber Goods & Tyres ; http://www.etrma.org/activities/chemicals/reach/exposure-scenarios)

Formaldehyde worker exposure during weighing and loading of Formaldehyde based resin as part of the Tyre and Rubber manufacturing process.

The job group Weighing & loading represents Formaldehyde worker exposure during weighing and loading of raw materials to the mixing chamber. Job group analysis on personal long term data results in a 90th percentile value of 0.26 mg/m^3 (N=10). As no personal short-term data are available on weighing/loading , the 95th percentile short-term value is estimated by multiplying the 90th percentile long-term value with a factor 2 (REACH Guidance R14).The calculated 95thpercentile value of short term weighing/loading data is 0.52 mg/m^3. Both long term and short term worker exposure values are below the reference values for Formaldehyde worker exposure of 0.50 mg/m^3 en 1.0 mg/m^3 respectively. The scenario is described in Table 19.

Table 19. Formaldehyde worker exposure during weighing and loading during Tyre & Rubber manufacturing

Use	**Scenario**	**Risk Management Measures**	**Type (unit)**	**Exposure value mg/m^3 (N)**
Tyre & Rubber manufacturing	Weighing & Loading chemicals Indoor 5% Formaldehyde	General ventilation (Natural and mechanical) +/- LEV	Personal Long-term (90th perc)	0.26 (N=10)
			Personal Short-term (95th perc)	0.52 (Estimation)

Formaldehyde worker exposure during mixing of Formaldehyde based resin as part of the Tyre & Rubber manufacturing process.

The job group Mixing represents Formaldehyde worker exposure during mixing and/or milling of raw materials in the mixing chambers. Job group analysis on personal long term data results in a 90th percentile value of 0.07 mg/m^3 (N=113) which is below the long term reference value of 0.50 mg/m^3. There are 6 short term mixing data available ranging from 0.067 to 0.093 mg/m^3. As the number of data is too small for conclusions, the 95th percentile short-term value is estimated by multiplying the 90th percentile long-term value with a factor 2 (REACH Guidance R14).The calculated short term 95thpercentile value is 0.14 mg/m^3. The estimated short term exposure value exceeds the available short term measurement values. Both values are however below the reference value of 1.0 mg/m^3. The scenario is described in Table 20.

Table 20. Formaldehyde worker exposure during the mixing part of Tyre & Rubber manufacturing

Use	**Scenario**	**Risk Management Measures**	**Type (unit)**	**Exposure value mg/m^3 (N)**
Tyre & Rubber manufacturing	Mixing Indoor 5% Formaldehyde	General ventilation (Natural or mechanical) +/- LEV	Personal Long-term (90th perc)	0.07 (N=113)
			Personal Short -term (95th perc)	0.14 (Estimation)

Formaldehyde worker exposure during shaping as part of the Tyre & Rubber manufacturing process.

The job group Shaping represents Formaldehyde worker exposure during the calendaring, molding and extrusion part of the Tyre and Rubber manufacturing process. Job group analysis on personal long term data results in a 90th percentile value of 0.07 mg/m^3 (N=157) which is below the long term reference value of 0.50 mg/m^3. There are 4 short term shaping data available ranging from 0.013 to 0.080 mg/m^3. As the number of data is too small for conclusions, the 95th percentile short-term value is estimated by multiplying the 90th percentile long-term value with a factor 2 (REACH Guidance R14).The calculated short term 95thpercentile value is 0.13 mg/m^3. The estimated short term exposure value exceeds the available short term measurement values. Both values are however below the reference value of 1.0 mg/m^3. The scenario is described in Table 21.

Table 21. Formaldehyde worker exposure during the shaping part of Tyre & Rubber manufacturing

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)
Tyre & Rubber manufacturing	Shaping Indoor Traces of Formaldehyde	General ventilation (Natural and/or mechanical) +/- LEV	Personal Long-term (90th perc)	0.07 (N=157)
			Personal Short -term (95th perc)	0.13 (Estimation)

Formaldehyde worker exposure during curing as part of the Tyre and Rubber manufacturing process.

The job group Curing represents Formaldehyde worker exposure during the curing or vulcanization part of the Tyre & Rubber manufacturing process. Job group analysis on personal long term data results in a 90th percentile value of 0.02 mg/m^3 (N=79) which is below the long term reference value of 0.50 mg/m^3. There are 3 short term curing data available ranging from 0.0048 to 0.080 mg/m^3.

As the number of data is too small for conclusions, the 95th percentile short-term value is estimated by multiplying the 90th percentile long-term value with a factor 2 (REACH Guidance R14).The calculated short term 95thpercentile value is 0.03 mg/m^3. The estimated short term exposure value is lower than the maximum measurement value of the available short term data. Both values are however below the reference value of 1.0 mg/m^3. The scenario is described in Table 22.

Table 22. Formaldehyde worker exposure during the curing part of Tyre & Rubber manufacturing

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)
Tyre & Rubber manufacturing	Vulcanization/Curing Indoor Traces of Formaldehyde	General ventilation (Natural and/or mechanical) +/- LEV No/partial enclosure	Personal Long-term (90th perc)	0.02 (N=79)
			Personal Short-term (95th perc)	0.03 (Estimation)

Formaldehyde worker exposure during finishing as part of the Tyre and Rubber manufacturing process.

Finishing represents Formaldehyde worker exposure during the final treatment to enhance their appearance or make them part of a multi-component article. There is a variety of different Finishing steps. Within the dataset provided by Tyre & Rubber manufacturers, 4 different subgroups are defined representing Finishing steps; Adherisation/gluing (N=22), Cutting (N=19), Tyre building (N=29) and Final inspection of the final rubber products (N=5). As short term data are lacking for all these final treatment processes, the 95th percentile short-term value is estimated by multiplying the 90th percentile long-term value with a factor 2 (REACH Guidance R14).

Job group analysis on personal long term Finishing - adherisation/gluing data results in a 90th percentile value of 0.08 mg/m^3 (N=22). The estimated short term 95th percentile is 0.15 mg/m^3. Both long term and short term values are below the reference values for Formaldehyde worker exposure .

Job group analysis on personal long term Finishing - Cutting data results in a 90th percentile value of 0.02 mg/m^3 (N=19). The estimated short term 95th percentile is 0.04 mg/m^3. Both long term and short term values are below the reference values for Formaldehyde worker exposure

Job group analysis on personal long term Finishing -Tyre building data results in a 90th percentile value of 0.03 mg/m^3 (N=29). The estimated short term 95th percentile is 0.06 mg/m^3. Both long term and short term values are below the reference values for Formaldehyde worker exposure.

The job group Finishing - Final inspection is represented by 5 measurement data ranging from 0.0030 to 0.016 mg/m^3. The number of data is insufficient for statistical analysis. Available measurements indicate that worker exposure values are below the reference value of 0.5 mg/m^3. The scenarios are summarized in Table 23.

Table 23. Formaldehyde worker exposure during the Finishing part of Tyre & Rubber manufacturing

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)
Rubber & Tyre manufacturing	Finishing; Adherisation/Gluing Indoor 0.53-7.4% Formaldehyde	General ventilation (Natural and/or mechanical) LEV No/partial enclosure	Personal Long-term (90th perc)	0.08 (N=22)
			Personal Short-term (95th perc)	0.15 (Estimation)
	Finishing; Cutting Indoor Traces of Formaldehyde	General ventilation (Natural and mechanical) +/- LEV	Personal Long-term (90th perc)	0.02 (N=19)
			Personal Short-term (95th perc)	0.04 (Estimation)
	Finishing: Tyre building Indoor Traces of Formaldehyde	General ventilation (Natural and mechanical)	Personal Long-term (90th perc)	0.03 (N=29)
			Personal Short-term (95th perc)	0.06 (Estimation)

Formaldehyde worker exposure during other worker activities within the Tyre and Rubber manufacturing industry

The dataset includes one personal long term measurement on cement operation with a measurement value of 0.049 mg/m^3. Two personal short term values are available on cement preparation ranging from 0.0125 – 0.080 mg/m^3. Available data are below the reference values for long term and short term worker exposure, but insufficient data are available for conclusions.

Latex preparation refers to a process in which textile is treated before being combined with rubber layers (Expert communication). Personal long term values on latex preparation range from 0.015-0.016 mg/m^3 (N=2). The Tyre and Rubber manufacturing industry provided 29 personal short term values on Latex preparation. Analysis results in a 95th percentile value of 0.08 mg/m^3 (N=29). Available personal long term data are below the reference value of 0.50 for long term worker exposure. Statistical analysis of short term Latex preparation data shows that short term exposure is well below the short term reference value of 1.0 mg/m^3.

Logistic activities are represented by 3 personal long term data ranging from 0.013 to 0.018 mg/m^3. There are no short term logistics data available. Available data are below the reference values for long term and short term worker exposure, but insufficient data are available for conclusions.

Cleaning & Maintenance activities are represented by 3 personal long term data ranging from 0.0086 to 0.043 mg/m^3. There are no short term cleaning & maintenance data available. Generally, cleaning and maintenance activities have a high exposure potential. Due to a lack of information on the source element during cleaning and maintenance (e.g. the amount of formaldehyde in products potentially available on or in installations that are cleaned or maintained), worker exposure cannot be estimated in any reasonable way. Taking the Formaldehyde worker exposure values from all process steps and activities of the Tyre and Rubber industry into account, it is assumed that Formaldehyde worker exposure during cleaning and maintenance activities will be below the reference value.

Formaldehyde worker exposure data and concentrations during production of Leather

The German association of producers of textile, paper, leather and fur auxiliaries and colourants, surfactants, complexing agents, antimicrobial agents, polymeric flocculants, cosmetic raw materials, pharmaceutical excipients and allied products (TEGEWA) provided us with 27 data points representing Formaldehyde worker exposure during leather production. The dataset can be subdivided in one group of 6 historical data points from 2001 (N=5) and 2005 (N=1) and one group of 21 recent data points representing Formaldehyde worker exposure in 3 different companies in 2012. Apart from the measurement value , the year of measurement and the division of measurement, no contextual information is available for the group of historical data points. The group of recent data points consist of 4 personal long term measurements and 17 stationary long term measurements.

As key exposure determinants including type of measurement (*e.g.* personal/stationary) and measurement duration are missing for the historical data, it is not possible to perform a basic and job group analysis on the total group of measurements. In the following section, the leather manufacturing process is described and illustrated with available data.

Leather manufacturing process and related Formaldehyde worker exposure

In the leather industry, some auxiliaries based on Formaldehyde are used as re-tanning and finishing agents. These auxiliaries include melamine Formaldehyde condensates, urea melamine formaldehyde condensates and naphthalene Formaldehyde condensates. Currently, the free Formaldehyde content of these condensates is below 0.1%.

Leather production using Formaldehyde based auxiliaries include weighing / dissolving of chemicals and subsequent loading/unloading of chemicals and solutions into tanning and dyeing drums. The tanned hides are subjected to different mechanical operations e.g. Sammying, Shaving, Setting-out, Milling and Drying followed by a finishing step which may include a spray application and drying step. The final product of finished leather is stored.

Potential worker exposure to Formaldehyde based auxiliaries in the leather industry can be expected during handling of solid chemicals (weighing/dissolving chemicals, dosing solid chemicals into tanning and dying drums), handling of chemicals in solution (loading/unloading of solutions of chemicals into tanning and dying drums), handling of treated leather (feeding/stacking the machines with tanned hides) and finishing of leather by spraying (Expert communication).

The dataset includes 6 historical measurement values. Three out of that 6 datapoints are from the Tannery with measurement values of 0.13 mg/m^3, 0.96 mg/m^3 and 1.71 mg/m^3 respectively. Hence, two of these values are above the long term reference value of 0.50 mg/m^3. The value of 1.71 mg/m^3 is above the short term reference value of 1.0 mg/m^3 as well. Formaldehyde contents in leather auxiliaries decreased a lot since 2001 (Expert communication). Due to a lack of contextual information, those values can however not be explained with a sufficient degree of certainty by the Formaldehyde content of the products used or any other exposure determinant. The three other historical datapoints are from Retannage and Spraying with corresponding measurement values below the reference values for long term and short term worker exposure.

Four out of 21 datapoints are personal long term data. Personal long term data represent handling of treated leather with measurement values from 0.021-0.035 mg/m^3 (N=3). The other personal long term measurement represents worker exposure during Finishing of leather by spraying with a measurement value of 0.0050 mg/m^3 (N=1).

Stationary long term data present Formaldehyde concentrations ranging from 0.0050-0.017 mg/m^3 (N=6) during handling of solid chemicals. Two stationary long term data points with a value of <0.010 mg/m^3 are available from handling of chemicals in solution. Formaldehyde concentrations measured by stationary long term measurements during handling of treated leather range from 0.0050-0.032 mg/m^3 (N=8). The stationary long term measurement value during Finishing of leather by spraying is 0.012 mg/m^3 (N=1).

Recent data from 3 different companies indicate safe use of Formaldehyde based products in the Leather industry. However, historical data show that Formaldehyde concentrations above the reference value were found within the last twenty years. Due to the absence of a robust dataset of personal long term data for all relevant worker exposure activities in the leather industry, risk assessment cannot be based on the available data. Table 24 summarizes the measurement data provided by Leather producers.

Table 24. Formaldehyde exposure levels provided by Leather producers

Use	Scenario	Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)
Leather manufacturing	Historical data (2001) Tannery	Unknown	Unknown (Range)	0.13 – 1.71 (N=3)
	Historical data (2005) Retannage, entrance	Unknown	Unknown (Raw value)	0.0070 (N=1)
	Historical data (2001) Spraying	Unknown	Unknown (Range)	<0.034 (N=2)
	Recent data (2012) Handling treated leather Indoor <0.1% Formaldehyde	Not reported	Personal long term (Range)	0.021-0.035 (N=3)
	Recent data (2012) Finishing leather by spraying Indoor <0.1% Formaldehyde	Spray cabin LEV	Personal long term (Raw value)	0.0050 (N=1)
	Recent data (2012) Handling solid chemicals Indoor <0.1% Formaldehyde	Natural ventilation +/- LEV	Stationary long term (Range)	0.0050 -0.017 (N=6)
	Recent data (2012) Handling chemicals in solution Indoor <0.1% Formaldehyde	Natural ventilation	Stationary long term (Range)	<0.010 (N=2)
	Recent data (2012) Handling of treated leather Indoor <0.1% Formaldehyde	Natural ventilation +/- LEV	Stationary long term (Range)	0.0050-0.032 (N=8)
	Recent data (2012) Finishing of leather by spraying Indoor <0.1% Formaldehyde	Spray cabin LEV	Stationary long term (Raw value)	0.012 (N=1)

Formaldehyde worker exposure data and concentrations during Foam production

One company provided three personal long term measurements from 2011 representing Formaldehyde worker exposure during the production of Foam. Mixing and blending are performed by a batch process followed by a continuous production of foam using a formulation with a Formaldehyde content of 2%. Data represent exposure of plant operators performing controls and sampling. Corresponding exposure values range from 0.17 to 0.24 mg/m^3 and are below the long term reference value of 0.50 mg/m^3.

As risk assessment cannot be based on this 3 measurements from one single company, worker exposure assessment is based on literature or modeled exposure values. Available user data are presented in Table 25.

Table 25. Formaldehyde exposure levels provided by Foam producers

Use	Scenario	Technical Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Foam production	Plant operation; control & sampling Indoor 2% Formaldehyde	Enclosed/Ventilated mixing vessels Controlled sampling Duration max 0.5 hours	Personal Long-term (Range)	0.17 -0.24 (N=3)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

Formaldehyde worker exposure data and concentrations during bonded fibers/mats production

Resins commonly are used to bind fiberglass, mineral wool, or shredded waste products such as cotton, wool, or polyester for use as structural and acoustical insulation for residential and commercial buildings, pipes, and industrial equipment. In fiberglass and mineral-wool insulation, UF resins often are used in conjunction with PF resins to inhibit the burning potential of the PF resins. In the construction industry, working with UFFI or fiberglass insulation manufactured using formaldehyde-based resins can result in formaldehyde worker exposure (NTP 2010).

One company provided 1 stationary long term data point from 2011 representing worker exposure during control of the production process of fibers/mats using a formulation with a Formaldehyde content of 0.1%. The reported value is below the reference value. As risk assessment cannot be based on this single source measurement, worker exposure assessment will be based on literature or modeled exposure values. The stationary data point and corresponding scenario is presented in Table 26.

Table 26. Formaldehyde exposure levels provided by Fibers/Mats producers

Use	Scenario	Technical Risk Management Measures	Type (unit)	Exposure value mg/m^3 (N)[1]
Fibers/Mats production	Process control Indoor 0.1% Formaldehyde	General ventilation (Natural and mechanical)	Stationary Long-term (raw value)	0.10 (N=1)

[1)] The exposure values have not been corrected for the effect of any respiratory protection that may have been used, unless the use of this RMM is described in the scenario.

4.5 Literature data on the use of Formaldehyde by downstream users

The call for user data did not result in enough data for a robust exposure assessment for the uses:

- Production of Fertiliser granules;
- Foams;
- Bonded particulates;
- Fibers/mats;
- Production of Paper;
- Use of resins in wood applications (e.g. glues) and
- Application of adhesives and coatings.

No literature was found on the use of Formaldehyde based products for production of Fertiliser granules, Leather, Foams and Bonded particulates meeting the requirements described in the methods of this study. Relevant literature sources describing the use of Formaldehyde based products for other downstream uses are described in Annex I. The usability of each source for worker exposure risk assessment in this study is described in Annex I as well. Formaldehyde exposure levels and usability of the data for risk assessment in this study are summarized per use in the following paragraphs.

Several databases describe Formaldehyde worker exposure over a long period. In this study, those databases are used indirectly by using the literature sources describing those databases. The following databases were described by the literature sources used:

- French COLCHIC database including Formaldehyde exposure values in nine French branches measured from 1987 to 1993.
- German database including Formaldehyde exposure values measured in the German paper and pulp industry from 1974 to 1993
- International database based on measurements carried out in 12 different countries between 1950 - 1994.
- Finnish database with Formaldehyde exposure measurements made by the Finnish Institute of Occupational Health during 1980 – 1994 in Finnish industry.
- Formaldehyde exposure data recorded in the U.S Integrated Management Information System (IMIS) between 1979 and 2001.

For details on the literature sources describing those databases is referred to Annex I. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products.

Literature data on the use of Formaldehyde formulations for production of Paper

Formaldehyde-based products can be used for various purposes in paper production. UF and MF resins can be added to fiber slurries before pressing to increase paper strength, and UF, MF, and PF resins often are used as coatings for various types of paper products. UF resins are used as adhesives in paper bags, cardboard, and sandpaper, and formaldehyde is used as a bactericide in some paper-coating agents. In paper-coating operations, the primary sources of emissions are from the dipping or coating operations and from drying ovens. Emissions from storage tanks and from areas where resin blends are prepared can also be a source of exposure (NTP 2010).[1]

Three relevant sources were identified for worker exposure to Formaldehyde during the production and of paper. Exposure values are considered indicative for Formaldehyde worker exposure in the paper industry. Available data indicate that the process of paper production results in Formaldehyde values above the reference values for Formaldehyde. As detailed scenario descriptions are absent, it is not possible to describe the circumstances that resulted in exposure above the reference values. However, the data show that the process steps of paper production, coating and impregnation (which is a different type of impregnation from that evaluated in the wood based panels industry) are the main sources of Formaldehyde exposure. Formaldehyde exposure values during preparation and cutting/packaging appear to be lower. The information is summarized in Table 27.

Table 27. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products for Paper production.

Use	Scenario	Type (unit)	Exposure value mg/m^3 (N)	Reference	Usability
Paper Production	Paper manufacturing	Personal long-term (90th perc)	0.65 (N=123)	Lavoué (2008)	Low
	*Preparation *Paper production *Roll coater *Impregnation/coating *Packaging	Stationary long-term (90th perc)	*0.11 (N =9) *0.94 (N=254) *1.0 (N=37) *1.3 (N=57) *0.16 (N=28)	Ahrens (1997)	Low
	Paper manufacturing	Personal short-term (95th perc)	1.43 (N=73)	Lavoué (2008)	Low
	*Pulping/Refining *Uncoated paper machine *Coated paper machine *Paperboard machine *Other machine *Calendering *Cutting	Stationary short-term (Range)	*0.00-3.81 (N=25) *0.05-0.56 (N=7) *0.01-12.16 (N=51) *0.22-2.70 (N=8) *0.00-8.11 (N=228) *0.00-61.40 (N=166) *0.00-1.35 (N=111)	Korhonen (2004)	Low

As operational conditions and risk management measures leading to safe use cannot be defined based on these literature data, additional model estimations need to be performed to investigate Formaldehyde worker exposure during paper production assuming specific risk management measures.

Literature data on the use of Formaldehyde formulations for Textile impregnation

Formaldehyde-based resins are used in the textile industry during the chemical finishing stage to impart crease-resistant and flame-retardant properties and to prevent shrinkage. The finishing

[1] The impregnation of decorative paper to laminate wood based panels is described and included in the estimations for the production of wood based panels.

process involves impregnating the fabric in an aqueous solution and then pressing it to remove the excess solution. In addition to gaseous formaldehyde exposure, workers can be exposed to formaldehyde bound to dust. The main factors that affect worker exposure to formaldehyde include the types of processes and products used, the presence and efficiency of fume hoods and emission collection systems, and the level of general ventilation. Jobs that may result in formaldehyde exposure include resin preparer, process operators (various types), colorist, and maintenance worker (NTP 2010).

Three relevant sources were identified for worker exposure to Formaldehyde during the impregnation of textile. Exposure values are considered indicative for Formaldehyde worker exposure in the textile industry. Available data indicate that the process textile impregnation results in Formaldehyde values above the reference values for Formaldehyde. As detailed scenario descriptions are absent, it is not possible to describe the circumstances that resulted in exposure above the reference values. The available data are summarized in Table 28.

Table 28. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products for Paper production.

Use	Scenario	Type (unit)	Exposure level mg/m^3 (N)	Reference	Usability
Textile impregnation	Not specified	Personal long-term (90th perc)	0.59 (N=126)	Lavoué (2008)	Low
		Personal & Stationary Long & Short (90th perc)	0.80 (N=14)	Niemaela (1997)	Low
		Personal short-term (95th perc)	2.29 (N=50)	Lavoué (2008)	Low
		Estimation based on 22 stationary short-term data (95th perc)	1.72	Lavoué (2006)	Low

As operational conditions and risk management measures leading to safe use cannot be defined based on these literature data, additional model estimations need to be performed to investigate Formaldehyde worker exposure during textile impregnation assuming specific risk management measures.

Literature data on the use of Formaldehyde formulations for wood processing

Occupational exposure during wood processing includes Formaldehyde exposure in the furniture industry and of professional carpenters manufacturing wood based products (e.g. cabinets). The main source of formaldehyde in this industry originates from finishes used on the furniture.

Wood processing can be generalized into four steps: (1) processing (sawing, sanding, assembly, inspection), (2) painting, staining, or varnishing (mixing, applying, drying, sanding, repair), (3) upholstery and installation of hardware, and (4) packaging and shipping.

Exposure determinants include the type of varnish used; process operating conditions, such as the nature of the spraying systems, drying time, and the location of operations; work methods employed; the presence and efficiency of varnishing booths and other local collection systems at the source; and the efficiency of the general ventilation system (IRSST 2006).

Tasks that can result in formaldehyde exposure include paint preparation, application of primers and varnishes, sanding between coats, unloading of furniture from ovens, repair tasks, installation of hardware, cleaning of application guns, and maintenance. Sources of formaldehyde release include releases from varnish use and storage, paint booths, furniture drying operations, and furniture storage. Jobs that may result in exposure include laborer, painter, finish operator, repair and maintenance personnel, finisher/shipper, supervisor, and office personnel (NTP 2010).

Six relevant sources were identified for worker exposure to Formaldehyde for the use of Formaldehyde based resins in wood applications. Exposure estimations performed by Lavoué (2006) are considered illustrative, the other sources indicative for Formaldehyde worker exposure in the wood processing industry. Mean values reported by Dingle (1999) are below the reference values of Formaldehyde. The 90th percentile value calculated from GM and GSD values presented by Priha (2004) is below the reference value as well. However, 90th and 95th from data presented by other sources are above the reference values. As detailed scenario descriptions are absent it is not possible to explain the differences in exposure values by the circumstances available during measurements. However, differences in values from operation of gluing machinery presented by Lavoué (2006) and values from processing of final MDF (Priha 2004) suggest that the specific task in combination with the Formaldehyde based products used results in different exposure values. Application of glue with a relatively high Formaldehyde content results in higher Formaldehyde exposure compared to processing of final wood panels in which resin and glue are cured. The available data are summarized in Table 29.

Table 29. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based resins in wood applications

Use	Scenario	Type (unit)	Exposure level mg/m^3 (N)	Reference	Usability
Use of resins in wood applications	Furniture manufacturing	Personal long-term (90 perc)	0.67 (N=155)	Lavoué (2008)	Low
	Cabinet manufacturing	Personal Long-term (Mean)	0.126 +/- 0.076 (N=unknown)	Dingle (1999)	Low
	Wood carpentry; operation of gluing machinery	Estimation on 45 Personal Long-term (90th perc)	1.59	Lavoué (2006)	Medium
	Furniture fabrication	Personal & Stationary Long & Short-term (95th percentile)	2.2 (N=23)	Carton (1995)	Low
	Furniture industry	Personal & Stationary Long & Short-term (90th perc)	0.88 (N=36)	Niemaela (1997)	Low
	Cabinet manufacturing *Bench *Drill *Saw *Tool cabinet *Timber rack *Office	Stationary Long-term (Mean)	*0.146 +/- 0.064 *0.177+/-0.126 *0.168+/-0.087 *0.179+/-0.090 *0.199+/-0.103 *0.124+/-0.060 (N=unknown)	Dingle (1999)	Low
	Wood carpentry; operation of gluing machinery	Estimation on 19 Stationary Long-term (90th perc)	3.45	Lavoué (2006)	Medium
	Small furniture factories; Grinding, Cutting, Sanding MDF containing UF resin	Stationary Long-term (GM and GSD)[1)]	GM=0.17; GSD=1.83 (N=7)	Priha (2004)	Low
	Furniture manufacturing	Personal short-term (95 perc)	2.51 (N=61)	Lavoué (2008)	Low

[1)] The number of samples was considered too small to make a reasonable estimation of the 90th percentile.

As operational conditions and risk management measures leading tosafe use during wood processing cannot be defined based on these literature data additional model estimations need to be performed to draw conclusions.

Literature data on the use of Formaldehyde formulations for production of Bonded fibers and fiber mats

Fiberglass insulation manufacturing involves six general steps: melting glass, spinning the molten glass into fibers, cooling and coating the fibers with a binder, forming the fibers into a pad, curing the binder (i.e., heating at 400°F to 600°F to set the binder), and packaging the insulation. The primary sources of formaldehyde release are from the fiber-coating process and the curing process (NTP 2010).

Three relevant sources were identified for worker exposure to Formaldehyde during the production of bonded fibers or fiber mats. Exposure values are considered indicative for Formaldehyde worker exposure during the production of bonded fibers or fiber mats. As the unit in which results are expressed are different for all three data sources, it is difficult to compare the results. However, results suggests that long-term Formaldehyde exposure levels are below the reference value for at least part of the production process of bonded fibers or fiber mats. Data from Milton (1996) indicate that exposure values from workers "fixed" to a specific part of the production process (e.g. forming attendant /leader, binder water leader/operator) exceed the exposure values from mobile workers (e.g. electrician, welder etc). The available data is summarized in Table 30.

Table 30. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products for production of Bonded fibers or fiber mats

Use	Scenario	Type (unit)	Exposure level mg/m^3 (N)	Reference	Usability
Production of bonded fibers or fiber mats	glass, fiber and plastics moulding	Personal long-term (95th perc)	0.67 (N=14)	Carton (1995)	Low
	Manufacturing Fiberglass with phenol-urea-formaldehyde *Forming attendant *Forming att leader *Binder water leader *Binder water operator *Pipefitter (fixed) *Forehearth operator *Machine operator *Crew (packaging) *Washwater tender *Mechanical repair *Electrician *Sheet metal worker *Welder *Pipefitter (mobile)	Personal Long-term (90th perc)	 *0.40 *0.17 *0.24 *0.12 *0.08 *0.31 *0.13 *0.07 *0.06 *0.06 *0.09 *0.06 *0.09 *0.05	Milton (1996)	Low
	*Basement *Forehearth *Curing ovens *Other areas	Stationary long-term (90th perc)	*0.42 (N=19) *0.97 (N=9) *0.53(N=9) *0.19(N=13)		
	Manufacturing of glass and mineral wool	Personal & Stationary Long & Short (Mean)	0.05 (N=2)	Niemaela (1997)	Low

As operational conditions and risk management measures leading to safe use during wood processing cannot be defined based on these literature data additional model estimations need to be performed to draw conclusions.

Literature data on the use of Formaldehyde based Paints/Coatings

Two relevant sources were identified for the application of Formaldehyde based adhesives and coatings. The combination of exposure values of both sources is considered suitable as basis for risk assessment. Safe use was demonstrated for roller painting based on personal long-term and short-term values. No short-term data are available for the application types Dip painting, Manual/Automatic spraying and curtain painting. As sufficient personal long-term data are present, the 95th percentile short-term value can be estimated by multiplying the 90th percentile long-term value with a factor 2 (REACH Guidance R14). Exposure values corresponding to dip painting and automatic spraying are below the reference values of personal long-term and short-term exposure.

Exposure values of manual spraying and curtain painting are above the reference values of personal long-term and short-term exposure. However, the workers did wear personal protective equipment during the measurements. This implies that the use of PPE is general practice during this kind of paint application. Prescription of half masks with a protection factor of 10 does results in real worker exposure values below the reference value. It should however be noted that Thorud (2005) shows contradictory results of spot test samples to investigate protection efficiency of charcoal filters against Formaldehyde exposure. Hence, special care should be taken in selecting suitable RPE during manual and curtain spraying. The available data is summarized in Table 31.

Table 31. Formaldehyde exposure levels published in literature associated with the application of Formaldehyde based adhesives and coatings

Use	Scenario	Type (unit)	Exposure level mg/m^3 (N)	Reference	Usability
Application of adhesives and coatings	Roller painting	Personal Long-term (90th perc)	0.09 (N=12)	Norback (1995)	Medium
	*Rolling/Brushing *Dip painting *Manual spraying *Automatic spraying *Curtain painting	Personal Long-term (90th perc)	*0.12 (N=16) *0.30 (N=9) *0.53 (N=284) *0.22 (N=58) *2.06 (N=25)	Thorud (2005)	High
	Roller painting	Personal Short-term (95th perc)	0.17 (N=5)	Norback (1995)	Medium

4.6 Exposure modeling on the use of Formaldehyde formulations by downstream users

The literature search did not result in sufficient suitable data for risk assessment for the uses:

- Production of Fertiliser granules;
- Foams;
- Bonded particulates;
- Leather;
- Fibers/mats and Textiles;
- Production of Paper and
- Use of resins in wood applications (e.g. glues).

Results of exposure estimations with corresponding circumstances are reported in Annex II. Worker exposure estimations for downstream use of Formaldehyde based products.

Results of worker exposure estimations for production of Fertiliser granules are below the reference value assuming realistic risk management measures.

Results of worker exposure estimations for industrial production and/or impregnation of Foams, Bonded particulates/fibers/mats, Leather, Textile and Paper are below the reference value. However, specific risk management measures (RMM), on top of LEV and (enhanced) general ventilation, need to be prescribed for PROCs 3 (Use in closed batch process (synthesis or formulation)), 4(Use in batch and other process (synthesis) where opportunity for exposure arises), 7 (Industrial spraying) and 24 (High (mechanical) energy work-up of substances bound in materials and/or articles). The necessary additional RMM are reduction of duration of activity and/or respiratory protection.

Results of worker exposure estimations for professional production of foams and use of resins in wood applications are below the reference value assuming stringent conditions for the following PROCs:

- PROC 5 (Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact));
- PROC8a (Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities);
- PROC8b (Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities);
- PROC10 (Roller application or brushing);
- PROC13 (Treatment of articles by dipping and pouring);
- PROC15 (Use as laboratory reagent);
- PROC21 (Low energy manipulation of substances bound in materials and/or articles);
- PROC23 (Open processing and transfer operations with minerals/metals at elevated temperature);
- PROC24 (High (mechanical) energy work-up of substances bound in materials and/or articles) and
- PROC25 (Other hot work operations with metals).

The stringent conditions include a potentially unfeasible reduction of the duration of activities to less than 1 hour or even less than 15 minutes and/or the use of respiratory protection on top of LEV and good general ventilation.

5 Risk assessment

Risk assessment is performed based on available data sources. Results are summarized in Table 32. The data or estimates that are used as the basis for conclusions are indicated by a cross ('X') in the cell. ...X...

Table 32. Summary of results worker exposure risk assessment based on available data sources

Life cycle stage	Identified use	Risk assessment		
		User	Literature	Model
Manufacture	Manufacture + aq. Solutions	X		
	Manufacture chemicals / resins / polymers	X		
Formulation	Formulation	X		
Industrial end use	Prod. Woodbased materials	X		
	Prod. Fertiliser granules			X
	Prod. Rubber	X		
	Prod. Foams			X
	Prod. Leather			X
	Prod. Paper			X
	Impreg. Textile			X
	Prod. Bonded particulates			X
	Prod. Bonded fibers/mats			X
	Use Adhesives/coatings		X	
Professional end	Use Adhesives/coatings		X	
	Prod. Foams			X
	Use resin wood applications			X

[1] The colour coding has the following interpretation:

Green: exposure values or estimates are below the reference value and are sufficient to indicate safe use;
Light green: Exposure values or estimates are below the reference value. Measured exposure values are however insufficient for sole basis of conclusions. Exposure estimates demonstrate safe use assuming specific risk management measures.
Grey: Part of the data are below and part of the data are above the reference value.
Orange: Exposure estimates are below the reference value, however, very stringent risk management measures need to be taken to reach these values.
Red: Exposure values presented in literature are above the reference value.

Manufacturing of Formaldehyde

Formaldehyde worker exposure during manufacturing of Formaldehyde is represented by a robust and representative set of user data.

Formaldehyde has been produced commercially since 1889 by catalytic oxidation of methanol. Currently, the two predominant production processes are a silver catalyst process and a metal oxide catalyst process. Worker exposure tasks that may result in formaldehyde exposure include collecting product samples for analysis, maintenance and repair operations, filter replacement and filling trucks and barrels (NTP 2010).

Exposure measurements representing Formaldehyde exposure during manufacturing are categorized into 4 job groups based on the contextual information provided by Formaldehyde manufacturers:

- Process control;
- Maintenance & Cleaning;
- Liquid transfer;
- Laboratory use.

Process control activities of workers within the Formaldehyde manufacturing industry include control of the Formaldehyde manufacturing process including sampling. Available long term process control data demonstrate safe use including all circumstances described by the data. Use of respiratory protection with a protection factor of 10 (RPE PF 10x) (*e.g*. half masks) needs to be prescribed to ensure peak exposure values below the reference value of 1.0 mg/m^3 during process control activities. Prescription of RPE PF 10x (*e.g.* half masks) is considered acceptable as risk management measure to protect workers from Formaldehyde peak exposure events. However, the present use of this risk management measure is confirmed by the contextual information of a limited number of short term process control data only. Hence, use of RPE PF 10x needs to be implemented as general risk management measure to ensure safe worker exposure during short term exposure events of process control activities as part of the Formaldehyde manufacturing process.

Maintenance & Cleaning activities of workers within the Formaldehyde manufacturing industry consist of service, repair, cleaning and/or filter changing as part of the Formaldehyde manufacturing process. Available long term maintenance & cleaning data demonstrate safe use including all circumstances described by the data. Use of RPE PF 10x needs to be prescribed to ensure peak exposure values below the reference value of 1.0 mg/m^3 during cleaning & maintenance activities. The present use of RPE PF 10x as specific risk management measure during short term cleaning & maintenance activities in general is confirmed by the available user data.

Liquid transfer activities of workers within the Formaldehyde manufacturing industry include loading/unloading of Formalin in tankers and rail cars. Analysis of long term liquid transfer data results in values just below the reference. This study presents a good practice assuming the use of a closed system and LEV. Use of RPE PF 10x needs to be prescribed to ensure peak exposure values below the reference value of 1.0 mg/m^3 during liquid transfer activities. The present use of RPE PF 10x as specific risk management measure during short term transfer activities in general is confirmed by the available user data.

Available data demonstrate safe use of Formaldehyde including the circumstances described by the data during laboratory use aiming at product analysis. Too few data points are available to properly assess the exposure during the laboratory Research & Development activities.

Manufacturing of Formaldehyde based resins / chemicals

Formaldehyde worker exposure during manufacturing of Formaldehyde based resins and other chemicals is represented by a robust and representative set of user data.

Resin / chemicals synthesis occurs by chemical reactions. Worker exposure tasks that may result in formaldehyde exposure within the Formaldehyde based resin / chemicals manufacturing industry include collecting of product samples for analysis, maintenance and repair operations, filter replacement, bagging, and filling trucks and barrels. (NTP 2010).

Exposure measurements representing Formaldehyde exposure during manufacturing of Formaldehyde based resins / chemicals are categorized into 7 job groups based on the contextual information provided by resin / chemicals producers;

- Process control;
- Process operation;
- Management;
- Maintenance & Cleaning;
- Solid transfer ;
- Liquid transfer;
- Laboratory use.

The job groups Liquid transfer and Laboratory use represent Formaldehyde worker exposure in both during both Formaldehyde as resin / chemicals manufacturing. Risk assessment of these job groups is described in the section above.

Process control activities of workers within Resin / chemicals manufacturing industry include control of the resin / chemicals manufacturing process including sampling. Available long term process control data demonstrate safe use including all circumstances described by the data. Analysis of short term process control data results in values above the reference. This study presents a good practice scenario assuming closed handling and sampling to ensure peak exposure values below the reference value of 1.0 mg/m^3 during process control activities.

Process operation represents Formaldehyde exposure of workers that operate resin / chemicals production reactors, charge raw materials and perform spray drying activities. Safe use of Formaldehyde during process operation activities is demonstrated in case of use a closed system and LEV. Use of RPE PF 10x needs to be prescribed to ensure peak exposure values below the reference value of 1.0 mg/m^3 during process control activities. The present use of RPE PF 10x as specific risk management measure during short term process control activities in general is confirmed by the available user data.

Management activities include supervision of the resin / chemicals production process mainly consisting of office work. Available data demonstrate safe use including the circumstances described by the data

Maintenance & Cleaning activities within the resin / chemicals manufacturing industry include service, repair, cleaning and/or filter change activities. Use of RPE PF 10x needs to be prescribed to ensure long term and peak exposure values below the reference values for Formaldehyde worker exposure. The present use of RPE PF 10x as specific risk management measure during short term process control activities in general is confirmed by the available user data.

Solid transfer activities consist of bagging and/or filling of solid resin. Available data demonstrate safe use including the circumstances described by the data.

Formulation

Formaldehyde worker exposure during Formulation is represented by a representative set of user data. Safe use is demonstrated under the circumstances described by the data.

Production of woodbased materials

Formaldehyde worker exposure in the wood panel production, due to the use of formaldehyde based resins, industry is represented by a robust and representative set of user data.

The wood panel production process includes pre-press, press and after-press operations.
The pre-press area is located outdoors and includes wood storage, wood preparation, screening/sifting and drying of wood particles. As this study focusses on Formaldehyde worker exposure due to handling of Formaldehyde based products, Formaldehyde worker exposure during wood storage, wood preparation and screening/sifting in the pre-press area are out of the scope of this study. Press operations are located indoors and include Glue preparation (glue kitchen), gluing, mat forming of wood particles and subsequent prepress, press and star cooler operations. The after-press area is located indoors as well and includes separate sanding/sawing, impregnation, lamination, packaging and storage areas. Analytical activities are performed in a separate laboratory building (Expert communication).

Panel production activities of workers include operation of gluing, mat forming, prepress, press, and star cooler process. Safe use of Formaldehyde based resins is demonstrated assuming use of RPE PF 10x during all activities in the press area. Use of RPE is not necessary during activities performed from the control room. The present use of RPE PF 10x as specific risk management measure during panel production activities in the press area in general is confirmed by the available user data.

Sanding & Sawing activities of workers within the wood panel industry consist of sanding line operations. Available long term sanding & sawing data demonstrate safe use including all circumstances described by the data. Use of RPE PF10x needs to be prescribed to ensure peak exposure values below the reference value of 1.0 mg/m^3 during sanding & sawing activities. The feasibility of RPE PF 10x as specific risk management measure during short term sanding & sawing activities in general is confirmed by the available user data.

Cleaning activities within the wood panel industry include degreasing, blowing and sweeping activities. Use of RPE PF 10x needs to be prescribed to ensure both long term and short term exposure values below the reference values. The feasibility of RPE PF 10x as specific risk management measure during cleaning activities in general is confirmed by the available user data.

Available data demonstrate safe use of Formaldehyde based resins and/or final wood panel products including the circumstances described by the data for the following parts of the process:

- Paper impregnation and subsequent lamination of panel board products;
- Maintenance activities including intervention of devices;
- Logistics including sorting and packing of final board products;
- Laboratory activities consisting of physical/chemical testing of panels.

Production of fertiliser granules

Safe use is demonstrated based on model estimates assuming reasonable conditions.
The limited user data that is available shows values below the reference value and supports the model estimates.

Production of rubber

Formaldehyde worker exposure during manufacturing of Tyre and Rubber is represented by a robust and representative set of user data.

Basic process steps of Tyre and Rubber manufacturing include storage, weighing and loading of raw materials to the mixing chamber. After mixing, compounds are given a specific shape during the process of shaping consisting of calendaring and extrusion steps. During subsequent curing, most of the substances react into a three dimensional polymer network. In the final treatment, the Tyre/Rubber products are subjected to further treatment to enhance their appearance or make them part of a multi-component article.

Available data demonstrate safe use of Formaldehyde based resins under the circumstances described by the data for all basic process steps of Tyre & Rubber manufacturing. Limited data on specific process steps (cement operation, latex operation) and general operations (cleaning and maintenance, logistics) are below the reference values for long term and/or short term worker exposure. Taking the Formaldehyde worker exposure values from all basic process steps and activities of Tyre and Rubber manufacturing into account, it is considered that Formaldehyde worker exposure during these specific and general activities will be below the reference value as well.

Production of foams (Industrial)

Safe use can be demonstrated with model estimates. Specific conditions or risk management measures are needed for some PROCs, e.g. reduction of duration of activities or respiratory protection. The limited user data that is available shows values below the reference value and supports the model estimates.

Production of leather

Formaldehyde worker exposure during manufacturing of Leather is represented by a set of 27 user data.

Leather production using Formaldehyde based auxiliaries include weighing / dissolving of chemicals and subsequent loading/unloading of chemicals and solutions into tanning and dyeing drums. The tanned hides are subjected to different mechanical operations e.g. Sammying, Shaving, Setting-out, Milling and Drying followed by a finishing step including a spray application and drying step. The final product of finished leather is stored.

Recent data from 3 different companies indicate safe use of Formaldehyde based products in the Leather industry. However, historical data show that Formaldehyde concentrations above the reference value might be possible. Due to the absence of a robust dataset of personal long term data for all relevant worker exposure activities in the leather industry, risk assessment cannot be based on the available data.

Safe use can be demonstrated with model estimates. Specific conditions or risk management measures are needed for some PROCs, e.g. reduction of duration of activities or respiratory protection.

Production of paper

Safe use can be demonstrated with model estimates. Specific conditions or risk management measures are needed for some PROCs, e.g. reduction of duration of activities or respiratory protection.

The major part of literature data is above the reference value.

Impregnation of textiles

Safe use can be demonstrated with model estimates. Specific conditions or risk management measures are needed for some PROCs, e.g. reduction of duration of activities or respiratory protection.

Data from literature shows values above the reference value.

4.10 Production of bonded particulates

Safe use can be demonstrated with model estimates. Specific conditions or risk management measures are needed for some PROCs, e.g. reduction of duration of activities or respiratory protection.

Production of bonded fibers/mats

Safe use can be demonstrated with model estimates. Specific conditions or risk management measures are needed for some PROCs, e.g. reduction of duration of activities or respiratory protection.

The limited user data that is available shows values below the reference value and supports the model estimates.

Part of the literature data is above the reference value and part of the literature data is below the reference value.

Use of adhesives and coatings (Industrial)

Safe use can be demonstrated based on representative literature data assuming use of RPE PF 10x for manual spraying and curtain painting.

Production of foams (Professional)

Safe use can for several PROCs only be demonstrated with rather stringent conditions and risk management measures, such as limitation of the duration of activities below 1 hour per day, often in combination with personal protection.

The limited user data that is available shows levels below the reference value. This suggests that at least in part of the relevant facilities the conditions and risk management measures are feasible.

Use of adhesives and coatings (Professional)

Safe use can be demonstrated based on representative literature data assuming use of RPE PF 10x for manual spraying and curtain painting.

Use of resins in wood applications

Safe use can for several PROCs only be demonstrated with rather stringent conditions and risk management measures, such as limitation of the duration of activities below 1 hour per day, often in combination with personal protection.

The major part of literature data shows values above the reference value.

6 Discussion

The Formaldehyde worker exposure assessment shows the Formaldehyde worker exposure and corresponding risk characterization ratios, by comparison with the reference values established as DNELs in the formaldehyde dossier composed by the formaldehyde consortium in 2010. Exposure is assessed using a combination of (in order of preference) data provided by the manufacturers and users, data found in literature and model estimates.

This report only describes the exposures of workers. No estimation has been made of potential combined exposure for workers that are also consumers living in situations with a concentration of formaldehyde. Such an estimation cannot realistically be made by summing reasonable worst cases for workers and consumers, since the probability that a worker working in the reasonable worst case exposure situation is also living in a reasonable worst case exposure situation is low and summing of these two reasonable worst cases will overestimate the real reasonable worst case population risk of workers that are exposed to formaldehyde. To make an appropriate combined exposure estimation, a probabilistic approach should be used, based on the exposure distributions of worker groups and the exposure distribution in the indoor environment. Potentially, this should be modified for a possible correlation between working in an a work situation with exposure to formaldehyde and living in specific indoor situations.

User data

In general, manufacturers and downstream users of formaldehyde put a large effort in the collection of worker exposure data. For a number of sectors rather large datasets were obtained that are considered to be representative for the situation in Europe, allowing a robust risk assessment. However, users from some other use sectors were not able to provide sufficient data within the timeframe of the project. In several downstream user industries the issue of formaldehyde exposure has not been considered to be very urgent and exposure levels have been assessed, largely qualitatively, to be sufficiently low. Therefore, useful recent data sets were not always available. Part of this can be explained because the reference value used by most companies so far is the national occupational exposure limit. If a number of measurements made years ago showed values below the respective national occupational exposure limit, the companies in good faith have concluded that there is no risk and may not have repeated measurements in the last decades.

For several uses there are too limited user measured data, but those data that are available show values below the reference value. An option to obtain more reliable conclusions on safe use in those cases, as well as in cases with no user measured data at all, is to actually gather more real user data, together with information on activities, products used, conditions and risk management measures and to redo the analysis of measured data for these uses. However, care should be taken to ensure sufficiently representative data sets that include those conditions that are typical or reasonable worst case and those risk management measures that are feasible.

Only recent data has been used. Pragmatically a limit of 20 years has been set, but in contact with (potential) providers of data it has been clearly indicated that it is more important that the data are relevant for the present processes, products used, conditions and risk management than that they are of a certain year. The majority of data received was much younger than 20 years.

In our analysis we decided to split the data in measurements of short duration (up to one hour) expected to relate to high exposure situations and measurements expected to be relevant for long term exposure (measurement duration more than one hour). Although the respondents were asked to indicate the reason for sampling, this field did generally not provide sufficient information to check whether measurements of short duration were indeed aimed at high exposure activities or situations. Therefore, it was not possible to specifically analyse measurements aimed at 'peak exposure' activities. If our assumption (that measurements of short duration relate to high exposure situations and measurements of longer duration relate to typical work day exposure) would be correct, the short term exposure values would be expected to be higher than the long term values. If short term exposure values are relatively low, compared to long term exposure values, resulting short term 95th percentile values are potentially an underestimation of real Formaldehyde exposure during peak exposure events. On the other hand, if a large part of the measurements of more than one hour would be aimed at high exposure situations, overestimation of shift exposure with calculated long term 90th percentile values is a possibility as well. Underestimation of short term exposure caused by using measurements that are not aimed at high exposure situations within a working day is considered unacceptable for risk assessment purposes. To prevent drawing conclusions on underestimated short term values, the 95th percentile short-term value is estimated by multiplying the 90th percentile long-term value with a factor 2 if short term exposure values are relatively low (REACH Guidance R14). In the data analysis it was seen that in several cases the distribution of results of measurements up to one hour was not (clearly) shifted to higher values compared to the distribution of measurements of the same situation for more than one hour. Apparently, either the measurements of short duration were not specifically aimed at high exposure situations or a substantial part of the measurements of longer duration was specifically aimed at high exposure situations. The potential underestimation of short term exposure during high exposure situations was prevented by using the estimation based on the long term measurement data. The potential overestimation of long term (full shift) exposure by using measurements that are potentially partly aimed at high exposure situations cannot be evaluated based on the available information, but this is considered not to be a major issue, because if this has occurred, the long term values will at least be conservative.

A number of general issues usually encountered in the analysis of measured data did also occur in this study. Firstly, questions as well as answers in a questionnaire are always subject to interpretation, either by the respondent or the data analyst. Therefore, there is substantial uncertainty regarding the true values of the determinants during the measurements, leading to a degree of misclassification. Misclassification leads to a lower probability of showing a true effect of a determinant. This partially explains the fact that determinants analysis does not always result in a difference between situations with different values for determinants, even if this would be expected. Furthermore, the fact that some of the analysed datasets or subsets are relatively small implies that the number of determinants for which there is sufficient contrast to enable showing their true effect is also small. Extension of the datasets may lead to a better differentiation in resulting values between different options for determinants. Due to interpretation differences between users of Formaldehyde based products and researchers, worker scenarios described in this report may be slightly different from the worker scenarios in practice. Especially the reported

Formaldehyde content in the products used may have been subject to misclassification. It is expected that several respondents did not report the level of free formaldehyde, but the total level, including the formaldehyde that is bound in the (polymerized) resin. Experts from the wood panel industry are convinced that realistic values are much lower than the highest values mentioned. Attempts could be made to clarify the interpretation of the respondents on this issue. To limit total uncertainty on percentages, it was considered that such a clarification should preferably then be sought for all data points. However, this would require a very substantial effort with a high probability of limited impact on the outcomes of the analysis. Therefore it was decided not to further investigate this issue.

Secondly, formaldehyde worker exposure is, like exposure to other substances, the result of a complex set of determinants and modifying factors, including the type of product used (e.g. Formaldehyde content), worker activities, occupational conditions (e.g. location) and risk management measures (localized controls, use of protective equipment). In this study it was attempted to account for such factors as much as possible. However, worker exposure is influenced by more aspects such as personal behavior, product volumes used, availability of other Formaldehyde sources (e.g. co-workers) (Tielemans, 2008). Besides that, company effects may result in differences between measured exposure values. The contextual information provided by users of Formaldehyde based products did not include information on all possible determinants influencing worker exposure. In some cases the information on the determinants requested in the questionnaire was not sufficiently provided.

Finally, formaldehyde worker exposure data provided by users were retrieved by a variety of sampling and analytical techniques. Currently, six analytical methods are listed for the measurement of formaldehyde in the NIOSH Manual of Analytical Methods: three methods for formaldehyde in air, one for aldehydes screening in air, one for organic and inorganic gases in air, and one for formaldehyde on dust. The use of different analytical methods results in differences in sensitivity and error in the measurement of formaldehyde across measurement studies (NTP 2010). Generally, analytical error is considered a relatively minor factor of uncertainty compared to true exposure variability (Tielemans, 2008). However, the specific effect of analytical error on the results presented in this risk assessment are not investigated, but some general considerations on measurement methods are described.

In the case of formaldehyde, it has been argued that some of the (older) methods are (very) unreliable, due to e.g. lack of sensitivity, effects of temperature and humidity or cross-sensitivity to other substances. The derivatisation methods with acetylacetone and DNPH are considered the most reliable method (Salthammer, Mentese and Marutzky, 2010). In the data gathering it was requested to indicate the principle of the measurement and analytical method. However, in many cases the reported method could not be related to one of the methods described by Salthammer, Mentese and Marutzky (2010) or to one of the standardized methods known, largely because internal descriptions of methods were provided or because the respondent apparently misinterpreted the question. An attempt to clarify this by asking for more information in case the principle of the method was not clear did not lead to sufficiently useful results. Therefore, it was decided not to do separate analysis for ‘best’ versus ‘less than optimal’ methods as the group of data sets classified as ‘best’ would be too small and not allow for a further analysis. A more precise analysis of exposures could be made if sufficient data were available using the best analytical methods. However, it is expected that the under- and overestimation of the different methods will balance out due to the large number of data points.

Literature data

Also from literature, only recent data has been used. In this case the date of measurement is relevant and not the date of publication (which can be years later). Whereas conditions and risk management measures were gathered for user data and questions were asked where needed, this was, of course, not an option for literature data. A rather large part of the literature found contained so limited information that the data had to be considered not useful. Also, data from outside of the EU was generally not considered useful, because the use of certain articles and products can vary substantially between e.g. the USA or Australia and the EU.

In many cases literature that was originally considered to be useful still contained so few details on exact activities, products used, conditions and risk management measures that the data could only be used as illustrative or indicative of exposure levels and not as the basis of exposure estimates.

In some cases it is difficult to conclude whether two literature sources actually describe (partly) the same datasets or really different data sets. This is e.g. the case for exposure in the Paper industry, where Korhonen (2004) describes an international database (including Germany) and Ahrens (1997) describes a German database. The German data may also have been included in the international database.

Some literature sources mention specific reasons for doing measurements. For example, Niemaela (1997) and Lavoué (2008) both state that measurements (in part of the cases) have been done when there was the expectation that there may have been high values. For most literature sources it is not clear whether or not this plays an important role. However, it is well known that there tend to be not a lot of measurements in situations that, in advance, are considered to be ‘safe’; researchers generally focus on situations for which they expect potential risks. Therefore, there may be a ‘measurement bias’ towards relatively worst case situations, that may even be not within usual conditions.

Literature data in this overview appears to show higher exposure values than user measured data and model estimates. This cannot be explained by information in the literature, because information is too scarce. An explanation can be that most literature describes relatively old situations (within the basic 20 year range used) and is no longer representative of the present situation. A tendency to measure there where known ‘problems’ or ‘issues’ exist (measurement bias) can also be a part of the explanation. Furthermore the conditions and risk management measures in the literature are often not described in enough detail to compare with those from either the user measured data or the model estimates. The relevance of such literature for describing safe use exposure situations is therefore rather limited.

Exposure modeling

When user data and literature data were not sufficient to draw conclusions, exposure modeling has been done, starting with the first Tier model ECETOC TRA. It appears to be possible to conclude on safe use for most activities in most uses. However, in some cases the conditions and risk management measures are relatively, or sometimes even very, stringent.

For industrial uses, the estimates made with ECETOC TRA may be too conservative. Many industrial processes do not require the workers to be close to the source (at least not for most of the day) and therefore estimates that (implicitly) assume a near field source may overestimate real exposure levels. This is certainly the case for activities covered by e.g. PROC3 (Use in closed batch process (synthesis or formulation)), which is largely a closed process. The fact that ECETOC TRA differentiates between industrial and professional situations may partly take account of the fact that workers in industrial situations are often further away from sources, but because it is a first Tier tool, it is not expected to take account of e.g. process operation from specific control rooms. The Advanced REACH Tool could be used to estimate exposures in these situations with less stringent conditions and risk management measures than those now assumed in ECETOC TRA. Because the estimates with ECETOC TRA were not considered really not-feasible, this has not been done.

For professional uses, there is no reason at this moment to assume that many of the ECETOC TRA estimates are too conservative. Automation and distance to the source can e.g. very often not be assumed in professional uses. Because of the non-standard relation between concentration of formaldehyde in a product and (partial) vapour pressure of formaldehyde in (aqueous) mixtures, for all percentage ranges of ECETOC TRA a specific vapour pressure has been entered and no (further) correction for percentage has been done. Therefore, the often used option of linear correction for percentage instead of the default categorical correction in ECETOC TRA is not relevant in this case. Without very specific information on relevant factors (such as very low use rates) there does not appear to be much reason to do further Tier model estimates for these professional uses. Because of the intended general conservative nature of Tier 1 models, the best option for improving the exposure estimates in professional use situations is to use proper measured datasets.

A general problem in exposure modeling is to model exposure of cleaning and maintenance of industrial installation in which a substance has been used. Exposure models rely largely on knowledge of types of activities and on factors that determine ‘source strength’ (specifically: amounts of products handled and percentage of substance in these products). That kind of data is often not available, cannot be easily measured and it is generally impossible to model this scientifically for cleaning and maintenance activities of (industrial) installations. Therefore, to conclude on safe cleaning and maintenance, proper measured datasets are the best way forward as well.

7 References

- Acton, Dr Bernard C. (2009) European Formaldehyde measurement campaign. Prepared for CEI-Bois aisbl; REF-Wood project Secretariat. Project No.2915.

- Ahrens, W., Jockel, K.H. (1997) Exposure to hazardous agents in the paper and pulp industry. Zentralblatt fur Arbeitsmedizin, Arbeitsschutz und Ergonomie, 47 (10), pp. 390-401.

- Carton, B. (1995) COLCHIC Chemical exposure database: information on lead and formaldehyde. Appl Occup Environ Hyg 1995; 10 (4): 345-350.

- Dingle, P., Tapsell, P. (1999) Cabinet-makers: Exposure to formaldehyde vapours. Journal of Occupational Health and Safety - Australia and New Zealand, 15 (3), pp. 249-252.
- Easy TRA Version 3.5.0

- ECETOC (2012). ECETOC TRA version 3: Background and Rationale for the Improvements. ECETOC. Technical Report No. 114, Brussels. ISSN-0773-8072-114.

- EPA Office of Compliance Sector Notebook Project (2005) Profile of the Rubber and Plastics Industry. Second Edition. Report number EPA/310-R-05-003.

- ETRMA website http://www.etrma.org/activities/chemicals/reach/exposure-scenarios Date 2013-02-27

- Excel 2010

- Formacare website http://www.formacare.org/index.php?page=applications. Date 2013-02-27.

- Fransman, W., Cherrie, J., Van Tongeren, M., Schneider, T., Tischer, M., Schinkel, J., Marquart, H., Warren, N., Kromhout, H., Tielemans, E. (2013) Development of a mechanistic model for the Advanced REACH Tool (ART) - Version 1.5. Updates previous version 1.0, June 2010. TNO report V9009. https://www.advancedreachtool.com/assets-1.5.12110.3/doc/ART%20Mechanistic%20model%20report_v1_5_20130118.pdf

- Guidance on information requirements and Chemical Safety Assessment R14, Occupational exposure assessment, ECHA, 2012

- Guidance on information requirements and Chemical Safety Assessment R12, Occupational exposure assessment, ECHA, 2010

- Hornung, R.W. and Reed L.D. (1990). Estimation of Average Concentration in the Presence of
- Nondetectable Values. Appl. Occup. Environ. Hyg. 5(1)

- IHSTAT version 2010

- Korhonen K, Liukkonen T, Ahrens W, Astrakianakis G, Boffetta P, Burdorf A, Heederik D, Kauppinen T, Kogevinas M, Osvoll P, Rix BA, Saalo A, Sunyer J, Szadkowska-Stanczyk I, Teschke K, Westberg H, Widerkiewicz K. (2004) Occupational exposure to chemical agents in the paper industry. Int Arch Occup Environ Health 2004; 77: 451-460.

- Krieger, R.E. (1964) Physical properties of aqueous formaldehyde. Litton educational. Pub. Inc. USA.

- Lavoué J, Vincent R, Gérin M. (2006) Statistical modelling of formaldehyde occupational exposure levels in French industries: 1986-2003. Ann Occup Hyg 2006; 50 (3): 305-321.

- Lavoué J, Vincent R, Gérin M. (2008) Formaldehyde exposure in U.S. industries from OSHA air sampling data. J Occup Environ Hyg 2008: 5: 575-587.

- Milton DK, Walters MD, Hammond K, Evans JS. (1996) Worker exposure to endotoxin, phenolic compounds, and formaldehyde in a fiberglass insulation manufacturing plant. Am Ind Hyg Assoc J 1996; 57 (10): 889-896.

- Niemelae R, Priha E, Heikkilae P. (1997) Trends of formaldehyde exposure in industries. Occup Hyg 1997; 4 (1): 31-46.

- Norback D, Wieslander G, Edling C. (1995) Occupational exposure to volatile organic compounds (VOCs), and other air pollutants from the indoor application of water-based paints. Ann Occup Hyg 1995: 39 (6): 783-794.

- Pubmed (http://www.ncbi.nlm.nih.gov/pubmed)

- Priha E, Pennanen S, Rantio T, Uitti J, Liesvuori J. (2004) Exposure to and acute effects of medium-density fiber board dust. J Occup Environ Hyg 2004: 1: 738-744.

- Scopus (http://www.scopus.com/home.url)

- SKC website http://www.skcinc.com/converter/converter.asp. Date 2013-02-26.

- Thorud S, Gjolstad M, Ellingsen DG, Molander P. (2005) Air formaldehyde and solvent concentrations during surface coating with acid-curing lacquers and paints in the woodworking and furniture industry. Journal of Environmental Monitoring, 7 (6), pp. 586-591.

- Tielemans, E., Noy, D., Schinkel, J., Heussen, H., Schaaf vd, D., West, J., Fransman, W.(2008) Stoffenmanager Exposure Model: Development of a Quantitative Algorithm. Ann. Occup. Hyg., Vol. 52. No. 6, pp. 443 – 454.

- US Department of Health and Human Services – National Toxicology program (2010) Final report on carcinogens – Background document for Formaldehyde.

Annex I. Formaldehyde exposure levels published in literature associated with the use of Formaldehyde based products

Ahrens (1997); Analysis of a database including Formaldehyde exposure values measured in the German paper and pulp industry from 1974 to 1993. The database includes both personal as stationary measurements. The text suggests that stationary long-term samples are presented in the results table. The 90th percentile exposure values are presented for each process step including Preparation of fiber materials; 0.11 mg/m^3 (N =9), Paper production; 0.94 mg/m^3 (N=254), Roll coater; 1.0 mg/m^3 (N=37), Impregnation and coating; 1.3 mg/m^3 (N=57) and Packaging 0.16 mg/m^3 (N=28).The authors conclude that the drier part of the paper machine as well as the coating of uncoated raw paper turned out to be the main points of Formaldehyde exposure.

Exposure values are considered indicative for worker exposure in the pulp and paper industry only. Data are robust and representative for the pulp and paper industry. However data are not actual and the results seem to represent source exposure instead of personal worker exposure.

Carton (1995); Analysis of the COLCHIC database including Formaldehyde exposure values in nine French branches measured from 1987 to 1993. A 95th percentile value of 0.67 mg/m^3 is presented based on 14 personal long-term exposure values during glass, fiber and plastics moulding.[2] A 95th percentile value of 2.2 mg/m^3 is presented from a combination of 23 personal and stationary long-term and short-term measurements during furniture fabrication. The authors mention that it is probable that most of the measurements are drawn from worst-case situations.

Exposure values are considered indicative for worker exposure only. Data numbers are considered sufficient and specific for the branches described. However, most of the data are not considered actual. Data during glass, fiber and plastics moulding represent personal exposure. As personal and stationary data are combined for furniture fabrication, those data are considered indicative, but not representative for personal exposure. Due to the absence of scenario information, it is not possible to judge the representativeness of these data for the whole European industry.

Dingle (1999); Fourteen small Australian cabinet manufacturers were measured using formaldehyde containing wood glues and finishes in 1991-1992. Both personal and stationary long-term measurements were performed. A mean Formaldehyde concentration of 0.103 +/- 0.062 ppm is presented for personal long-term measurements. Mean values of stationary long-term measurements are presented for 6 different locations; Work bench 0.119 +/- 0.052 ppm, Drill 0.144 +/- 0.103 ppm, Saw 0.137 +/- 0.071 ppm, Tool cabinet 0.146 +/- 0.073 ppm, Timber rack 0.162 +/- 0.084 ppm, Office 0.101 +/- 0.049 ppm.

This exposure is value is considered indicative for worker exposure only. The personal measurements represent personal worker exposure but the number of data underpinning the mean

[2] Actually, the table in the publication states that these are values in µg/m^3. However, this does not appear to fit with the described conclusions on probability of exposure above the reference value used in the publication. In our view these probabilities are much too high when the values were actually in µg/m^3. We have therefore assumed that this is a simple mistake in the publication and that the unit should be mg/m^3.

value is missing. Mean values are not suitable to calculate reasonable worst-case 90th percentile values for cabinet manufacturing. The actuality of the data is low and information on key exposure determinants is missing. Furthermore, these data retrieved from Australian small and medium enterprises are not considered representative for European Formaldehyde exposure during cabinet manufacturing.

Korhonen (2004); Results of an international epidemiological (IARC) study of workers in the pulp and paper industry in which exposure measurements were assembled carried out in 12 different countries between 1950 - 1994. Both European countries (e.g. Germany, Netherlands, Spain) as Canada and USA supported the study. The Arithmetic mean, Median, Minimum and Maximum values calculated from short-term Formaldehyde exposure data are presented by department in the pulp and paper industry; Pulping, refining, etc. of stock; 0 – 3.1 ppm (N=25), Newsprint and uncoated paper machine; 0.04-0.46 ppm (N=7), Fine and coated paper machine; 0.01-9.9 ppm (n=51), Paperboard machine; 0.18-2.2 ppm (N=8), Paper/paperboard machine from more than one of above categories; 0- 6.6 ppm (N=228), Calendaring or on-machine coating; 0- 50 ppm (N=166), Winding, cutting, grading; 0 -1.1 ppm (N=111). Hence, highest Formaldehyde values are measured in fine and coated-paper departments and on-machine coating departments.

Exposure values are considered indicative for worker exposure in the pulp and paper industry only. Data are robust and representative for the pulp and paper industry. However data are not actual, information on key exposure determinants is missing and the results seem to represent source exposure instead of personal worker exposure.

Lavoué (2006): Analysis an extract of data from COLCHIC, the French national OEDB, of all concentrations of Formaldehyde. Formaldehyde data retrieved from different industries and tasks are analyzed with extended linear mixed-effects models to elaborate a multi-sector picture of formaldehyde exposures. Lavoué presents GM values of personal and stationary samples taken in several industries in 2002. Besides that, predicted GM and GSD values are presented using mixed-effect models based on the specific samples from 2002. Geometric mean values of personal long-term and short-term samples during Wood carpentry work; operation and monitoring of gluing machinery are 0.52 mg/m^3 (N=45) and 0.81 mg/m^3 (N=19) respectively. Corresponding predictions of GM and GSD values are 0.39 mg/m^3 and 3.0 for long-term exposure and 0.42 mg/m^3 and 3.6 for short-term exposure. Lavoué presents 22 short-term stationary samples from the textile industry with a GM value of 0.24 mg/m^3. Corresponding predicted GM and GSD values are 0.13 mg/m^3 and 4.8 respectively.

The raw personal exposure data presented by Lavoué are considered actual, robust and representative for personal worker exposure. As GM values do not represent a reasonable worst-case exposure among industry, those values are not useful for risk characterization. Theoretically, reasonable worst- case values can be calculated using the predicted GM and GSD values. It was however noticed that the predicted GM values were low compared to the raw GM values. Hence, calculations based on the predicted GM and GSD values may result in an underestimation of the Formaldehyde exposure within industry. Hence, 90th and 95th percentile calculations based on these predicted GM and GSD values can be used to illustrate worker exposure, but are not useful as basis for risk assessment. Stationary short-term data are presented for the textile industry. As those data do not represent personal exposure, those data are considered indicative for exposure in the textile industry only.

Lavoué (2008): Analysis of Formaldehyde exposure data recorded in the U.S Integrated Management Information System (IMIS) between 1979 and 2001. Geometric mean and GSD values of both personal long-term and short-term data are presented from several industries. Textile manufacturing; Long-term GM 0.10 mg/m^3, GSD 4.0(N=129), Short-term 0.20 mg/m^3, GSD 4.4 (N=50). Furniture manufacturing; Long-term GM 0.14 mg/m^3, GSD 3.4 (N=155), Short-term GM 0.32 mg/m3, GSD 3.5 (N=61). Paper manufacturing Long-term GM 0.11 mg/m^3, GSD 4.0 (N=123), Short-term 0.20 mg/m^3, GSD 3.3 (N=73).

Exposure values are considered indicative for worker exposure only. Data are robust and specific for several industries. As part of the dataset is more than 20 years old, the actuality of the results is not known. Furthermore, these data retrieved from US companies are not considered representative for European worker exposure in related industries.

Milton (1996) studied Formaldehyde exposure in a fiberglass wool insulation manufacturing plant in which phenol-urea-formaldehyde binder was used. Mean, GM and GSD results of stationary long-term measurements are presented for different production departments; The basement GM 63 µg/m^3 , GSD 4.42 (N=19); Forehearth GM 414 µg/m^3, GSD 1.95 (N=9) ; Curing ovens GM 87 µg/m^3, GSD 4.09 (N=9) ; Other areas GM 22 µg/m^3, GSD 5.46 (N=13). Mean, GM and GSD values for personal long-term measurements are presented by job group and related production department for fixed location workers; Basement –forming attendant GM 26.8 µg/m^3, GSD 8.2; Forming att leader GM 74.9 µg/m^3, GSD 1.9; Binder water leader GM 11.3 µg/m^3, GSD 10.9; Binder water operator GM 46.2 µg/m^3, GSD 2.1; Pipefitter GM 50.3 µg/m^3, GSD 1.4. Forehearth – operator GM 45.9 µg/m^3, GSD 4.4. Curing ovens – machine operator 67.4 µg/m^3, GSD 1.7. Mobile worker exposure results are presented as well; Crew (packaging) GM 11.6 µg/m^3, GSD 4.1; Washwater tender 36.3 µg/m^3, GSD 1.5; Mechanical repair GM 13.2 µg/m^3, GSD 3.4; Electrician GM 20.2 µg/m^3, GSD 3.1; Sheet metal worker GM 15.6 µg/m^3, GSD 2.7; Welder GM 26.0 µg/m^3, GSD 2.6; Pipefitter GM 21.8 µg/m^3, GSD 1.9.

Exposure values are considered indicative for worker exposure only. Personal data numbers are sufficient and representative for personal exposure. However, data represent exposure in one plant. The location of the plant is not clear but research group from US and comparison with US limit values suggests that data are from a plant located in the US. Those data are not considered representative for the European fiberglass wool industry.

Niemela (1997); Analysis of a database of exposure measurements made by the Finnish Institute of Occupational Health during 1980 – 1994 in Finnish industry. The database includes measurements from the textile industry, furniture industry, manufacturing of plastic products, glass and mineral wool . Mean, Median, 10th and 90th percentile values of combined personal and stationary exposure measurements with measurement duration of 10-100 min are presented. Summary statistics are provided for the whole time span (1980 -1994) and for separate periods; 1980-1985, 1986-1990 and 1991-1994. Fourteen samples from the textile industry dated 1991-1994 are presented with a 90th

percentile value of 0.80 mg/m^3. The furniture industry is represented by 36 samples from the period 1991-1994 with a 90th percentile value 0.88 mg/m^3. Manufacturing of glass and mineral wool is represented by two samples from 1991-1994 with a mean value of 0.05 mg/m^3. All sampling dates from data representing the manufacturing of plastic products are from 1980-1990.

Exposure values are considered indicative for worker exposure only. Data from the textile and furniture industry are considered actual and robust. Limited or no actual data are available from the glass /mineral wool and plastic industry respectively. All measurement types (e.g. personal, stationary, long-term, short-term) are combined in the analysis. The researchers separated personal and stationary measurements and conclude that personal exposure values exceed the stationary values below 0.5 mg/m3. Hence, combined exposure values are not representative for personal worker exposure. Scenario descriptions are absent and the researchers state that data are obviously biased towards worst case situations because monitoring is performed because of poor working conditions, experienced irritations or suspected occupational diseases. Hence, these data does not seem to represent reasonable worst-case worker exposure values in the European industry.

Norback (1995) identified and quantified Formaldehyde exposure of Swedish house painters during application of water based paint by roller painting from April 1989 to December 1991. Minimum and Maximum values, Arithmetic mean, Geometric mean and Geometric standard deviation values are presented for both personal long-term and personal short-term values. Personal long-term measurements range from <0.03-0.10 mg/m^3. Corresponding GM and GSD values are 0.04 and 1.9 respectively (N=12). Personal short-term values range from <0.03-0.14 mg/m^3. Corresponding GM and GSD values are 0.08 and 1.6 respectively (N=5).

Estimations of the 90th percentile exposure value using the presented GM and GSD values can be used to illustrate worker exposure during roller painting, but are not useful as basis for risk assessment. Data are considered representative for personal worker exposure. Sampling dates are 22 years back, but it is considered that the scenario (Indoor roller painting of houses) is an actual scenario. Information on the product composition is missing in this article. Hence, it is not possible to compare the formaldehyde content of the water based paint used with current product formulations. It is however assumed that formaldehyde content of this type of products did not increase over time. In practice, application of paints/coatings is performed by different types of application (e.g. roller painting, spray painting, dip painting, curtain painting). The emission potential of spray painting is higher than roller painting. Exposure values during spray painting are missing in this article. Besides that, the number of data is limited. Therefore, these data cannot be used for a reasonable worst- case estimation of worker exposure in the European paint industry.

Priha (2004); Investigation of Formaldehyde exposure in three small furniture factories during processing of pure wood or MDF containing urea-formaldehyde resin glue by grinding, cutting and sanding. Summary statistics including GM and GSD values are presented of stationary long-term samples. The formaldehyde seems to be higher among the workers who machined MDF board; GM 0.17 mg/m^3, GSD 1.83 (N=7) compared to the workers who processed pure wood ;GM 0.10 mg/m^3, GSD 1.75 (N=9). The authors explain the difference by the content of formaldehyde-based binding agent in the MDF board and the use of acid-curing lacquers by factories processing MDF board.

Exposure values are considered indicative for personal formaldehyde exposure in the furniture industry only as these stationary data are not considered representative for personal worker exposure. As the number of factories and data is limited, it cannot be assured that those data represent a reasonable worst-case case situation for the European furniture industry.

Thorud (2005): Personal task exposure measurements on Formaldehyde during application of acid-curing lacquers and paints. Measurements took place in 27 Norwegian woodworking and furniture factories over a 3 year period in the late 1990's. Exposure ranges, GM and GSD values are presented from work tasks with a mean duration of 141 min. Formaldehyde values during curtain painting range from 0.08-1.48 ppm with a GM value of 0.51 ppm and a GSD of 2.53 (N=25). During manual spray-painting, formaldehyde values range from 0.01-1.14 ppm with a GM value of 0.15 ppm and a GSD value of 2.29 (N=284). Automatic spray painting results in formaldehyde values ranging from 0.04-0.24 ppm with corresponding GM and GSD values of 0.11 ppm and 1.48 ppm respectively (N=58). Formaldehyde exposure during rolling/brushing ranges from 0.05-0.16 ppm with a GM value of 0.07 ppm and GSD value of 1.32 (N=16). Dip painting results in Formaldehyde exposures ranging from 0.10-0.27 ppm with corresponding GM and GSD values of 0.16 ppm respectively and 1.39 (N=9). Curtain painting machine operators were exposed to the highest concentrations of Formaldehyde explained by the use of old, open machines without ventilation of the curing and drying zones and with inadequate ventilation of the rooms. The researchers state that concentrations during curtain painting were significantly higher than concentrations observed during automatic and manual spray painting, rolling/brushing and dip painting. Besides that, automatic spray painting appeared to be significantly different from manual spray painting, while manual spray painting also was significantly different from rolling/brushing. During painting operations, the workers did wear personal protective equipment of different kinds. This implies that real exposure values were lower than the measured concentrations. However, results of spot test samples to investigate protection efficiency of charcoal filters against Formaldehyde exposure were contradictory. Hence, the real protection efficiency of the equipment used is uncertain.

Estimations of the 90^{th} percentile exposure value using the presented GM and GSD values are considered suitable for risk assessment on the application of formaldehyde containing adhesives and coatings. Data are considered actual, robust and representative for personal worker exposure. Factories involved in the study were selected on the use of acid-curing lacquers and paints. It is assumed that different brands and product compositions were involved in the study giving a representative picture of Formaldehyde based paints and coatings. As the study covers factories of different sizes and different painting application methods during the use of acid-curing lacquers and paints, data are considered representative for European paint industry.

Annex II. Worker exposure estimations for downstream use of Formaldehyde based products

Use	Scenario	Risk Management Measures	Model	Type (unit)	Worker exposure value (mg/m^3)
Production of Fertilizer granules	62% Formaldehyde Indoor, 300 degrees Industrial Production PROC 1,2	Closed process (360 min) + dedicated transfer with medium level containment (120 min) RPE PF 10x for dedicated transfer	ART	Personal Long-term (90th perc)	0.28
			ART	Personal Short-term (95^{th} perc)	0.56
	62% Formaldehyde Indoor Industrial Transfer Solid, low dustiness PROC 8a	LEV	TRA	Personal Long-term (75th perc)	0.050
		LEV	TRA	Personal Short-term (95^{th} perc)	0.20
	62% Formaldehyde Indoor, 60 degrees Industrial Transfer PROC 8b	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.47
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95^{th} perc)	0.19
Industrial production of *Foams *Bonded particulates *Bonded fibers/mats *Paper Impregnation of *Leather *Textile	1-5% Formaldehyde Indoor, 100 degrees Industrial Production PROC 1,2	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.19
		LEV and enhanced general ventilation	TRA	Personal Short-term (95^{th} perc)	0.75
	1-5% Formaldehyde Indoor, 100 degrees Industrial Production PROC 3,4	LEV and enhanced general ventilation + max 4 hours OR RPE PF 10x	TRA	Personal Long-term (75th perc)	0.45 OR 0.08
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95^{th} perc)	0.18
	1-5% Formaldehyde Indoor, 60 degrees Industrial Mixing/Blending PROC 5	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.19
		LEV and enhanced general ventilation	TRA	Personal Short-term (95^{th} perc)	0.75
	1-5% Formaldehyde Indoor, 60 degrees Industrial Calendaring PROC 6	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.19
		LEV and enhanced general ventilation	TRA	Personal Short-term (95^{th} perc)	0.75

Use	Scenario	Risk Management Measures	Model	Type (unit)	Worker exposure value (mg/m^3)
	1-5% Formaldehyde Indoor, 20 degrees Industrial Spraying PROC 7	LEV and enhanced general ventilation + max 1 hours OR RPE PF 10x	TRA	Personal Long-term (75th perc)	0.38 OR 0.19
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.15
	1-5% Formaldehyde Indoor, 20-60 degrees Industrial Transfer PROC 8a, 8b, 9	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.38
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.15
	1-5% Formaldehyde Indoor, 20 degrees Industrial Rolling/Brushing PROC 10	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.38
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.15
	1-5% Formaldehyde Indoor, 60 degrees Industrial Dipping/Pouring PROC 13	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.38
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.15
	1-5% Formaldehyde Indoor, 60 degrees Industrial compression/extrusion PROC 14	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.19
		LEV and enhanced general ventilation	TRA	Personal Short-term (95th perc)	0.75
	1-5% Formaldehyde Indoor, 20 degrees Industrial cutting/cold rolling/assembly Solid, high dustiness PROC 21	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.30
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.12
	1-5% Formaldehyde Indoor, 60 degrees Industrial processing of minerals Solid high dustiness, PROC 22 - 23	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.30
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.12
	1-5% Formaldehyde Indoor, 20 degrees Industrial cutting/sanding Solid, high dustiness PROC 24	LEV and enhanced general ventilation + Max 4 hours	TRA	Personal Long-term (75th perc)	0.36
		LEV and enhanced general ventilation +RPE PF 10x	TRA	Personal Short-term (95th perc)	0.14

Use	Scenario	Risk Management Measures	Model	Type (unit)	Worker exposure value (mg/m^3)
	1-5% Formaldehyde Indoor, 60 degrees Industrial welding/soldering Solid, high dustiness PROC 25	LEV and enhanced general ventilation	TRA	Personal Long-term (75th perc)	0.15
		LEV and enhanced general ventilation	TRA	Personal Short-term (95th perc)	0.60
Professional *production of foams *use of resins in wood applications	1-1.5% Formaldehyde Indoor, 60 degrees Professional Mixing/Blending PROC 5	LEV and good general ventilation + Max 1 hour OR RPE PF 10x	TRA	Personal Long-term (75th perc)	0.35 OR 0.18
		LEV and good general ventilation + RPE PF 10x	TRA	Personal Short-term (95th perc)	0.14
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Transfer PROC 8a	LEV and good general ventilation + Max 1 hour + RPE PF 10x	TRA	Personal Long-term (75th perc)	0.09
		LEV and good general ventilation + RPE PF 10x	TRA	Personal Short-term (95th perc)	0.36
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Transfer PROC 8b	LEV and good general ventilation + Max 1 hour OR RPE PF 10x	TRA	Personal Long-term (75th perc)	0.18 OR 0.09
		LEV and good general ventilation (RPE PF 10x only in case of using RPE option as RMM for long term exposure)	TRA	Personal Short-term (95th perc)	0.70
	1-1.5% Formaldehyde Indoor/Outdoor, 20 degrees Professional Rolling/Brushing PROC 10	Outdoor + Max 1 hour + RPE PF10x Indoor with good general ventilation + Max 1 hour + RPE PF 10x	TRA	Personal Long-term (75th perc)	0.44 OR 0.44
		Outdoor + RPE PF20x Indoor with good general ventilation + RPE PF 20x	TRA	Personal Short-term (95th perc)	0.88 OR 0.88
	1-1.5% Formaldehyde Indoor, 60 degrees Professional Dipping/Pouring PROC 13	LEV and good general ventilation + Max 1 hour	TRA	Personal Long-term (75th perc)	0.35
		LEV and good general ventilation + RPE PF 10x	TRA	Personal Short-term (95th perc)	0.14
	1-1.5% Formaldehyde	LEV and good general ventilation +	TRA	Personal Long-term	0.18 OR 0.09

Use	Scenario	Risk Management Measures	Model	Type (unit)	Worker exposure value (mg/m^3)
	Indoor, 60 degrees Professional Lab use PROC 15	Max 1 hour OR RPE PF 10x		(75th perc)	
		LEV and good general ventilation (RPE PF 10x only in case of using RPE option as RMM for long term exposure)	TRA	Personal Short-term (95th perc)	0.70
	1-1.5% Formaldehyde Indoor, 20 degrees Professional cutting/cold rolling/assembly Solid, high dustiness PROC 21	LEV and good general ventilation + Max 15 min OR RPE PF 10x	TRA	Personal Long-term (75th perc)	0.28 OR 0.28
		LEV and good general ventilation + RPE PF 10x	TRA	Personal Short-term (95th perc)	0.11
	1-1.5% Formaldehyde Indoor, 60 degrees Industrial processing of minerals Solid, high dustiness PROC 23	LEV + Max 15 min OR RPE PF10x	TRA	Personal Long-term (75th perc)	0.40 OR 0.40
		LEV + PF 10x	TRA	Personal Short-term (95th perc)	0.16
	1-1.5% Formaldehyde Indoor, 20 degrees Professional cutting/sanding Solid, high dustiness PROC 24	LEV and good general ventilation + Max 15 min OR RPE PF10x	TRA	Personal Long-term (75th perc)	0.35 OR 0.35
		LEV and good general ventilation + PF 10x	TRA	Personal Short-term (95th perc)	0.14
	1-5% Formaldehyde Indoor, 60 degrees Industrial welding/soldering Solid, high dustiness PROC 25	LEV + Max 1 hour OR RPE PF10x	TRA	Personal Long-term (75th perc)	0.40 OR 0.20
		LEV + PF 10x	TRA	Personal Short-term (95th perc)	0.16

[1] In some cases, safe use is demonstrated using two different worker scenarios. In that cases, the result column includes two different values.