SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Formaldehyde

EC No 200-001-8

CAS No 50-00-0

Evaluating Member State: France
Co-evaluating Member State: The Netherlands

Dated: 7 June 2019

Template Version 2.1
March 2015

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Year of evaluation in CoRAP: 2013

Before concluding the substance evaluation a Decision to request further information was issued on: 6 October 2015

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

A joint Evaluation was performed by the French MSCA (ANSES) and the Dutch MSCA (RIVM) with France (FR) leading the Evaluation and being the responsible competent authority in the meaning of Article 45(2) of REACH.

Substance Evaluation was targeted on human health.

ANSES was in charge of assessing risks for workers and RIVM for consumers.

Formaldehyde was originally selected for substance evaluation in order to clarify concerns about:

- CMR properties
- Exposure of workers
- High (aggregated) tonnage
- Wide dispersive use
- Consumer use

The initial grounds for concern for consumer exposure via indoor air were based on uncertainties about the actual exposure via consumer products. This concern may be justified because, while formaldehyde is not contained in most sources, it can be emitted it as a result of chemical reaction (hydrolysis of resins/glues) or combustion. As only for consumer products containing more than 0.1% of formaldehyde Exposure Scenarios have to be developed (Article 14(2)), the CSR did not contain any information on consumer exposure emitted by, for example, wood based panels or cooking.

During the evaluation also other concerns related to worker health were identified. The additional concerns were:

- Risks for workers based on formaldehyde toxicity
- Risks related to presence of methanol

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Formaldehyde is widely addressed in existing and forthcoming legislation. Many international and national policy measures on formaldehyde have been taken to reduce consumer and worker exposure levels.

The regulatory context is presented in details in the separate Risk Management option Analysis (RMOA) for worker health (the conclusion when available will be published in the public activities coordination tool (PACT)). In particular, formaldehyde has a harmonised classification as Carc. 1B with a CLP concentration limit of ≥ 0.1%, which triggers regulatory consequences under several EU regulations. Some uses of formaldehyde also fall under the Biocidal Product Regulation Regulation (EU) 528/2012.

In 2016, SCOEL revised its recommendation of an Occupational Exposure Limit (OEL) for formaldehyde (SCOEL 2016).

Consumer use

During the reaction time for industry on the SEv Decision request, Commission requested ECHA to develop a restriction proposal for formaldehyde. As requested by the Commission, the restriction will focus on the placing on the market and use of formaldehyde and formaldehyde releasers in mixtures and articles for supply to

consumers. The restriction proposal will be developed in parallel and in liaison, with the Netherlands' work on consumer exposure to formaldehyde.

EU regulation for wood based panels

Several European countries started in 1980 to regulate formaldehyde emissions (Zeleniuc, 2016).
A voluntary panel industry agreement to produce only emission class E1 (0.1 ppm boards) for wood-based panels is in since 2006. The emission classes E1 and E2 (European Standard EN 13986) for wood products used in construction were established in Europe in 2004.

European formaldehyde limits (two emission classes) for wood based panels are summarized in the harmonized standard EN 13986:
E1 ≤ 8mg/100g dry board;
E2 > 8 - ≤ 30 mg/100g dry board.

In Table 1 the limits of formaldehyde release for E1 and E2 class according to European standards are presented.

In Germany, Austria, Denmark and Sweden formaldehyde concentration limits of 6.5 mg/100 g dry board are obligatory.
The European Panel Federation (EPF) derived its own standards:

- for PB (particle board): 4mg/100g and
- for medium density fibreboard (MDF): 5 mg/100g (thickness > 8 mm) (Markessini 2010).

In December 2016, EPF announced the so called European Low Emission Standard (E.LES), which sets different emission limits for different product groups. Under E.LES the formaldehyde emission limit for fibreboard and OSB is consistent with E1 (= 0.1 ppm or 0.124 mg/m^3) but is set to a lower value of 0.065 ppm (= 0.08 mg/m^3) for particleboard and plywood. E.LES is available to all EPF members for use but without any form of obligation (EPF, 2017).

EU standards

European Standard (EN 13986) related to factory production control for wood based panels, emission classes E1 and E2:

Table 1: Formaldehyde emission class E1 according to EN 13986

		Panel product		
		Unfaced	Unfaced	Coated, overlaid or veneered
		Particleboard OSB MDF	Plywood Solid wood panels LVL	Particleboard OSB MDF Plywood Solid wood panels Fibre boards (wet process) Cement bonded particleboards LVL
Initial type testing [a]	Test method	ENV 717-1		
	Requirement	Release ≤ 0,124 mg/m^3 air		
Factory production control	Test method	EN 120	EN 717-2	
	Requirement	Content ≤ 8 mg/100 g oven dry board See NOTE 3	Release ≤ 3,5 mg/m^{2}h or ≤ 5 mg/m^{2}h within 3 days after production	

[a] For established products, initial type testing may also be done on the basis of existing data with EN 120 or EN 717-2 testing, either from factory production control or from external inspection.

(EPF 2017)

Table 2: Formaldehyde emission class E2 according to EN 13986

			Panel product		
			Unfaced	Unfaced	Coated, overlaid or veneered
			Particleboard OSB MDF	Plywood Solid wood panels LVL	Particleboard OSB MDF Plywood Solid wood panels Fibre boards (wet process) Cement bonded particleboards LVL
Initial type testing	either	Test method	ENV 717-1		
		Requirement	Release > 0,124 mg/m^3 air. See NOTE 4.		
	or	Test method	EN 120	EN 717-2	
		Requirement	Content > 8 mg/100 g to ≤ 30 mg/100 g oven dry board	Release > 3,5 mg/m^{2}h to ≤ 8 mg/m^{2}h or > 5 mg/m^{2}h to ≤ 12 mg/m^{2}h within 3 days after production	
Factory production control		Test method	EN 120	EN 717-2	
		Requirement	Content > 8 mg/100 g to ≤ 30 mg/100 g oven dry board	Release > 3,5 mg/m^{2}h to ≤ 8 mg/m^{2}h or > 5 mg/m^{2}h to ≤ 12 mg/m^{2}h within 3 days after production	

(EPF 2017)

Constructions Product Directive

"*ANNEX I: BASIC REQUIREMENTS FOR CONSTRUCTION WORKS*

3. Hygiene, health and the environment

The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:

(a) the giving-off of toxic gas;

(b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air; (…)"

(EU 2011)

Biocidal Product Regulation

Formaldehyde has been approved to be used as disinfectant for the following product types:

Product type 2: Disinfectants and algaecides not intended for direct application to humans or animals.

"*Formaldehyde is used by professionals as a disinfectant in private and public health areas (product type 2) by wiping and mopping (prophylactic purposes) as well as by fogging/fumigation in cases of danger of an epidemic. After fogging/fumigation formaldehyde is neutralised with ammonia. As neutralisation product, white powdered methenamine is formed and deposits on the surfaces.*
The general use is assumed to take place on a daily basis whereas the use in a case of danger of an epidemic is assumed to take place only once a year."

(BPC 2017)

Product type 3: Veterinary hygiene

"Formaldehyde is applied as a disinfectant for veterinary hygiene in areas in which animals are housed, kept or transported to prevent animal diseases (PT3). This includes the disinfection of animal housings, the disinfection of vehicles in epidemic cases, the disinfection of eggs used for breeding (not for human consumption) as well as the disinfection of animals´ feet. Formaldehyde is used by professionals as aqueous solution by spraying, wiping and fogging/fumigation."

(BPC 2015)

Formaldehyde is under review to be used as **Product type 22** - Embalming and taxidermist fluids.

(ECHA 2018)

Cosmetic product regulation

Formaldehyde is approved to be used in:

- nail hardening products in concentration up to 5%
- cosmetics (except oral products) in concentrations up to 0.2%
- oral products in concentrations up to 0.1%

(EU 2009)

EU Commission Report on Ethanol and Gel Fireplaces

In 2015, EU Commission has published a report on ethanol and gel fireplaces, where several devices were examined for, amongst others, formaldehyde emission. From some ethanol fireplaces, formaldehyde emissions resulted in indoor air concentrations above 100 µg/m^3.

In the recommendations on the safe use of ethanol and gel fireplaces, aiming on reduction of VOC (Volatile Organic Chemicals) in general, the following points are listed (amongst others):

- Obligatory specific tests defined in the product standards, before their placing on the market, as is required for most of fuel burning appliances.
- Introducing national standards for aldehydes emission, next to presently required only for CO (and NOx for the French standard).
- Requirements for proper ventilation, construction details and proper manual.

(EC 2015)

According to the WHO guidelines for indoor air quality formaldehyde concentration should not exceed 0.1 mg/m^3.

(WHO 2010)

3. CONCLUSION OF SUBSTANCE EVALUATION

3.1. Conclusion related to worker health

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions related to worker health, as summarised in the table below.

Table 3

CONCLUSION OF SUBSTANCE EVALUATION FOR WORKERS	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level to be discussed in the RMOA	X
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

Anses identified in the course of evaluation a number of uses for which risks arise for workers as shown in the section 7.13.

As a result, the expected target of a potential Risk Management Options (RMOs) for formaldehyde would be at least both the formal setting of appropriate DNELs for short and long-term exposures (0.3 and 0.6 ppm respectively) and the control of the on-site occupational exposures to formaldehyde below these exposure limits. The respect of such limits is defined herein as the Risk Reduction Strategy (RRS) to be achieved. This may require one or a combination of the following solutions: substitution of the substance within the same/similar process, alternative process, stop of use, closed systems and automation, collective protective equipments, personal protective equipments, , etc.

This RRS has been implemented in France since the 1st of January, 2007, by a French decree of 13 July 2006 (JORF, 2006) adding processes emitting formaldehyde to the list of substances, preparations and processes considered as carcinogenic. If substitution is not technically possible, exposures should be reduced as low as possible, aiming at respecting current regulatory French OELs (0.5 ppm for long-term and 1 ppm for short-term exposures). According to measures from the French COLCHIC database (Mater, 2016), formaldehyde occupational exposures decreased between the 2000-2006 period and the 2007-2013 period following the implementation of this decree. If the COLCHIC exposure values are compared to the DNELs proposed by the FR eMSCA (0.3 and 0.6 ppm respectively), as it was done in section 7.13.1, the number of occupational sectors at risk decreased from 24 to 17 for long-term exposures between 2000-2006 and 2007-2013, with a reduction of more than 50% of formaldehyde exposures in numerous occupational sectors identified by COLCHIC database. This analysis underline the efficiency of the implementation of this French decree, showing that the control of the on-site occupational exposure to formaldehyde below exposure limits is relevant as a risk reduction strategy.

Therefore, several RMOs are discussed in the RMOA related to worker health (to be published) aiming at assessing their potential effectiveness and appropriateness in implementing such EU wide setting and control.

3.2. Conclusion related to consumer health hazard

Table 4

CONCLUSION OF SUBSTANCE EVALUATION FOR CONSUMER	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level	X
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	X
Other EU-wide measures	X
No need for regulatory follow-up action at EU level	

For further details on conclusions for consumer see chapter 4.

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

Formaldehyde has a harmonised classification under the CLP Regulation (see section 7.6.1). In particular, the classification of formaldehyde as Carc. 1B has entered into force on 1st January 2016. To date, no other proposal for CLH has been submitted and no revision is planned.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Formaldehyde meets the SVHC 57(a) criterion.

The impact of an SVHC identification to address the risks demonstrated is affected by the intermediate status of formaldehyde for some uses. As formaldehyde is confirmed by Industry to be an intermediate in the production of resins and the synthesis of chemicals, such uses would be excluded from authorisation (99% of the uses).

However, the intermediate uses of formaldehyde cannot exempt it from SVHC identification.

This identification would send a strong signal about its hazardous nature and would trigger the obligations related to the substances formally identified as such. Companies would need to comply with the requirements (in REACH Article 7 and 33) to provide extended Safety Data Sheets (eSDS), including hazard information, risk management measures and exposure scenarios to producers and importers and to communicate information on safe use to customers and consumers for substances in articles.

This option is further discussed in the RMOA related to worker health (the conclusion when available will be published in the public activities coordination tool (PACT)).

4.1.3. Restriction

Considerations related to worker health

The ability of REACH restriction to be a suitable measure to address the risks demonstrated for the uses of formaldehyde depends on several factors among which the intermediate status of these uses. Concerning the production of resins and synthesis of chemicals, these uses could not be covered by a restriction, except if formaldehyde is proved to be an isolated transported intermediate. However, no detailed information on occupational risks related to such uses is available in REACH registration dossiers. Transportation of formaldehyde is regulated and controlled under UN Regulation. In that case, the establishement of appropriate BOELs[2] in the CMD Directive[3] would be the sole suitable RMO to address these risks (see discussion under section 4.1.4 below). Only the other uses of formaldehyde could be then covered by REACH restriction, namely the remaining 1% claiming by Industry related for instance to "healthcare applications".

In conclusion, a REACH restriction could be feasible and could take different forms to limit the workers exposure. Sectorial Biocidal Regulation seems also particularly well fitted to address the potential risks in embalming fluids (thanatopraxy). However, the non-intermediate uses eligible to a REACH restriction are in principle limited.

This option is further discussed in the RMOA related to worker health (the conclusion when available will be published in the public activities coordination tool (PACT)).

Considerations related to consumer health

Information provided by the Registrant(s) in the registration dossiers show that there are situations in which indoor air formaldehyde concentrations are higher than the DNEL of 100 µg/m^3 as proposed by the Registrant(s). Note that for the purpose of this evaluation,

[2] Binding Occupational Exposure Limit

[3] Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens and Mutagens Directive)

the comparison between measured or calculated indoor concentrations and the Registrant(s) DNEL was sufficient to justify the concern. The outcome of an exposure scenario modeling, included in the additional report (July 2013) provided by the Registrant(s) was also taken into account.

The exposure was modelled in an indoor scenario combining different sources (wood-based construction ceiling, flooring and a piece of furniture: large wardrobe), which resulted in an exposure of 93 µg/m^3. Concluding, addition of a single, minor source (for example another piece of furniture) will already result in exceeding of the DNEL.
As a response to the requirements from the Decision, the registrants provided a report on emission rates of formaldehyde (Salthammer 2019a, Salthammer 2019b). This report gives additional information on sources and their contributions, and was used to select the proper restriction targets.
Emission sources were divided into temporary (mainly combustion sources) and continuous. Combustion sources (cooking, candles, incense, fireplaces) are outside the scope of REACH, and therefore they should be handled within other regulations.
The available information indicates the need for a further decrease of the exposure to formaldehyde. The eMSCA concluded, based on data provided for continuous sources, that further lowering formaldehyde emissions from wood based panels will have the most benefitial impact on indoor air quality.
A proposal for restriction is being drafted by ECHA, upon request of the Commission. This document proposes restriction on placing on the market or using articles if formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1.

Other sources of indoor formaldehyde emissions – articles (for example furniture), mixtures (for example paints) – are also taken by ECHA under consideration for possible restrictions.

To efficiently enforce emission limits, a reliable and reproducible measurement methodology (including guidance on measurement time points) is needed. There are currently several measurement methods for formaldehyde emissions used for establishing emission classes:

- The perforator method (EN 120) is a simple method, specific for formaldehyde emissions measurements, used on daily basis in wood based panels factories to check the quality of their products.
- The chamber method (EN 717-1) is performed usually at specialized laboratories and additional formaldehyde emissions measurements are done twice a year. Wood based panels samples are sent to laboratories for the quality check. This method is also specific for formaldehyde emissions measurements.
- EN 16516 is a horizontal test method mandated by the European Commission that determines the specific emission rate of volatile organic compounds including formaldehyde from a construction product into indoor air. The test result is expressed as a concentration in the air of a reference room.

The reliability of the methodology should be taken into account in the discussion of the restriction.

4.1.4. Other EU-wide regulatory risk management measures

Considerations related to worker health : OSH regulation

Since specifically designed for risk management of chemicals at the workplace, both CAD 98/24/EC and Directive CMD 2004/37/EC appear in principle relevant for implementing European OELs for formaldehyde. Setting binding OELs (BOEL) rather than indicative OELs (IOEL) is seen by ANSES as a relatively more efficient tool in order to allow stricter OELs

across the EU and to oblige Industry to comply with these requirements. Indeed, IOELs are not considered foreseeable to rely on a shared agreement between all Member States for transposing these values with a binding status. Moreover, as formaldehyde complies with the CMD considering its carcinogenic harmonised classification, Directive CMD 2004/37/EC is considered better suited than Directive 98/24/EC to achieve the RRS defined herein.

In addition, as formaldehyde is confirmed by Industry to be an intermediate in the production of resins and the synthesis of chemicals, such uses would be excluded from authorisation (99% of the uses) and these uses would not be subject to a restriction except if formaldehyde is proved to be a transported isolated intermediate. For these uses, the workplace legislation such as defined by CMD Directive and the establishment of appropriate BOELs would be the sole suitable RMO to address these occupational risks. However, the pressure for substitution is not so evident in practice and Directive CMD 2004/37/EC may be seen as a less efficient measure for this specific purpose compared to alternative RMOs.

In conclusion, inclusion of formaldehyde in the Directive 2004/37/EC on Carcinogens and Mutagens at work is considered consistent with the objective of the RRS stated above. Indeed, it would, depending on the value agreed on, generally decrease the accepted exposure level at the EU level. Stricter measures could be decided later on if needed, based on results from on site surveys and national controls.

The OELs recommended by SCOEL for formaldehyde (SCOEL 2016) and the DNELs established by ANSES in this evaluation report are in agreement and are included in the Resolution of the European Parliament voted on 27 March 2019 and proposing to amend the CMD Directive.

This option is further discussed in the RMOA related to worker health (the conclusion when available will be published in the public activities coordination tool (PACT)).

Considerations related to consumer health

The provided information demonstrates the large contribution to the overall formaldehyde indoor air concentration of combustion sources, such as cooking, burning candles and ethanol fireplaces. Temporary sources are outside the scope of the current Annex XV restriction proposal. Further EU-wide regulatory risk management measures may be considered, e.g. by inclusion of requirements in national standards, warnings (candles and incense) and advise on consumer products or limiting maximum capacity of fuel tanks in e.g. fire places.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

Not relevant.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Worker

The report of ANSES regarding the analysis of the most appropriate risk management option for formaldehyde has been subjected to public consultation[4]. The final RMOA of the

[4] http://www.consultations-publiques.developpement-durable.gouv.fr/consultation-publique-sur-le-rapport-de-l-anses-a1421.html

FR MSCA related to worker health is to be published in the public activities coordination tool (PACT).

Consumer

As indicated above, advised follow-up action is the proposal of a restriction for articles that may release formaldehyde in indoor environment. The drafting of a proposal has already been started by ECHA, on request of the European Commission.

Table 5

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
Annex XV dossier for restriction	2018	ECHA

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

A joint Evaluation was performed for formaldehyde by the French MSCA (ANSES) and the Dutch MSCA (RIVM) with France (FR) leading the Evaluation and being the responsible competent authority in the meaning of Article 45(2) of REACH.

Substance Evaluation was targeted on human health.

ANSES was in charge of assessing risks for workers and RIVM for consumers. Some parts of the evaluation report relate specifically to the assessment of worker health within the scope of FR evaluation. Other parts of the evaluation report are dedicated by NL to consumer health.

Formaldehyde was originally selected for substance evaluation in order to clarify concerns about:

- CMR properties
- Exposure of workers
- High (aggregated) tonnage
- Wide dispersive use
- Consumer use

The initial concerns on human health, wide dispersive use and consumer exposure were related the uncertainty in the actual consumer exposure due to formaldehyde concentrations in indoor air. Formaldehyde is present in preparations like detergents, coatings and adhesives. Regarding consumer uses, the concentration of formaldehyde in this type of preparations is restricted to 0.1%.There are many products not containing formaldehyde as such, but having a relatively high potential for releasing formaldehyde into indoor air such as wood based panels, insulation foams and textile.

During the evaluation also other concerns related to worker health were identified. The additional concerns were:

- Risks for workers based on formaldehyde toxicity
- Risks related to presence of methanol

Table 6

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
- Risk for workers based on formaldehyde toxicity	In the initial phase of the evaluation in 2014, no need for further information was identified to characterise risks for workers. Risks for workers are identified for several uses and a RMOA has been initiated to discuss the most appropriate risk management options.

- Risk related to the presence of methanol	In the initial phase of the evaluation in 2014, some formaldehyde solutions were registered with a content of methanol of more than 10% w/w. It triggers a classification as Flammable Liquid, Cat. 3. In none of the exposure scenarios, the risks originating from the flammability and other physicochemical hazard were specifically addressed. Registrants were required to address and discuss the hazards and risks related to the presence of methanol above 10% w/w, when relevant. In the follow-up evaluation of 2018, hazards and risks related to the presence of methanol above 10% w/w were addressed, when relevant.
- Human health/CMR	Formaldehyde is a carcinogen. No further information and no further action needed.
- Consumer exposure via indoor air	The information available on formaldehyde emission sources in indoor air is considered sufficient to justify a restriction proposal. Major emission sources have been identified. Further steps needed for the proper control of formaldehyde indoor concentrations are proposed, see section 4.1.

7.2. Procedure

The scope of the evaluation was restricted to human health. NL eMSCA was in charge of the assessment of irritation and characterisation of risks for consumers. FR eMSCA was in charge of the assessment of other human health hazards and characterisation of risks for worker health.

7.2.1. Workers exposure – assessment by FR eMSCA

The initial phase of evaluation (March 2013-March 2014) was based on the updated registration dossiers submitted by 16 July 2013. In addition, data from the French COLCHIC database were considered. The COLCHIC database (Mater, 2016) collects occupational exposure measurements carried out by the chemical laboratory services of CARSAT (Health insurance) and the INRS institute (French institute for occupational safety and health). The use of the database and the statistical analysis for formaldehyde exposures were done by INRS on two periods of time : 2000-2006 and 2007-2013.

At the end of the initial phase of evaluation, a concern for workers was identified and a RMOA was initiated. In parallel, a Decision was sent to Registrants on 6 October 2015. The Decision required registrants to consider hazards and risks related to the presence of methanol above 10% w/w as an additive in some aqueous solutions of formaldehyde (request 1). Registrants were asked to update their registration dossiers with the required information before 13 October 2017.

The second phase of evaluation started on 11 October 2017. The initial evaluation was updated to further refine worker DNEL and RCR, in the light of SCOEL discussions in 2016 and revision of ANSES's reference values for formaldehyde (ANSES, 2018). In addition, updated compositions were considered on the basis of registration dossiers submitted by 7 June 2018, in particular with regard to their methanol content and its consequences.

The characterisation of toxicological hazards was not updated in this second phase of evaluation.

7.2.2. Consumer exposure – assessment by NL eMSCA

The Dutch MSCA was in charge of the assessment of consumer exposure.

The initial phase of the substance evaluation by eMSCA (March 2013-March 2014) was based on the updated registration dossiers available in July 2013. The evaluation resulted in a concern on consumer exposure. The available information from the registration dossier(s) and an additional report (Marquart H. 2013) provided by the Registrants suggest that formaldehyde is omnipresent in indoor air and that consumers may be exposed to concentrations close to and, in some cases, exceeding the DNEL of 0.1 mg/m3 (as derived by the Registrants). Because of this concern, it was necessary to gather sufficient data that allow the performance of a risk assessment, for which the contribution from different sources is needed.

A Decision (ECHA 2015) with a request for information was sent to the Registrants on 6 October 2015. The Decision required Registrants to provide a review of literature data on the emission rates (in µg/m^2/h), comprising time-dependency (where available) for the major sources and their relative contribution to the total indoor air concentration of formaldehyde. Registrants were asked to update their registration dossiers with the required information before 13 October 2017. See for details on requirements: https://echa.europa.eu/documents/10162/1cc58141-07a2-49ed-9ef9-c6c4fcf9d74b.

The follow-up evaluation was started on 11 October 2017. The registrants provided a report on emission rates of formaldehyde (Salthammer 2017), which was evaluated by the Dutch eMSCA. Part of the data from this report was subsequently published in two open-source publications (Salthammer 2019a, Salthammer 2019b). The eMSCA considered the supplied data to be sufficient for proposing further steps of regulatory risk management, and the Substance Evaluation is completed in the form of a Conclusion Document.

7.3. Identity of the substance

Table 7

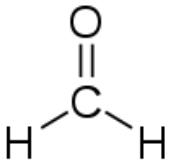
SUBSTANCE IDENTITY	
Public name:	Formaldehyde
EC number:	200-001-8
CAS number:	50-00-0
Index number in Annex VI of the CLP Regulation:	605-001-00-5
Molecular formula:	CH_2O
Molecular weight range:	30.0263
Synonyms:	Agent T106 CKA-121 CKA-1634 CKA-1636 CROPOL UF100F CROPOL UF100H

	Formaldehyd FORMALDEHYD REIN 37% FORMALDEHYD REIN 39% Formaldehyde Formaldehyde Formaldehyde (8CI, 9CI) Formaldehyde (8Cl, 9Cl) Formaldehyde gas Formaldehyde Solution Formaldehyde solution Formalin ormalin, formaldehyde, formalith, formol, formic aldehyde, methyl aldehyde, methylene oxide, methanal, oxomethane, oxymethylene, morbicid, paraform, methaldehyde Formalith Formaldehyd Formaldehyde (8Cl, 9Cl) Formic aldehyde Formol Methanal Methyl aldehyde Methylene oxide Oxomethane Oxymethylene Formaldehyde, gas Morbicid Paraform Methaldehyde Sadeform Formaldehyde Formaldehyde Solution 30 - 55% Formaldehyde, gas Formaldehydlösung 30 - 55% Formaldeide Formalin formalin technical formalin, formaldehyde, formalith, formol, formic aldehyde, methyl aldehyde, methylene oxide, methanal, oxomethane, oxymethylene, morbicid, paraform, methaldehyde Formalina techniczna 55% Formalith Formic aldehyde Formol GENFOR 37 KEC-2185CA75 KEC-2190 KEF-6154M85 KHI-900 KOSABOND-R50N KPA-1350 KPA-1800 KPR-1302 KPT-S1503 Methaldehyde Methanal Methyl aldehyde Methylene oxide Morbicid Oxomethane Oxomethylene Oxymethylene Paraform POLYTONE AP 108 POLYTONE AP 109 POLYTONE AP 109 D POLYTONE AP 110 POLYTONE AP 111 POLYTONE AP 111 HM POLYTONE AP 112 POLYTONE AP 112 SR POLYTONE AP 114

	POLYTONE AP 120 POLYTONE AP 130 Sadeform

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



Multiconstituent/UVCB substance/others

The gaseous state of formaldehyde is not stable, so the formaldehyde is produced as an aqueous solution. Furthermore, in concentrated aqueous solution formaldehyde is present in the form of oligomers. The polymerisation is reversible by dilution and methanol is added to inhibits polymer precipitation. The content of water is listed both under impurities and additives. According to the substance definitions given in REACH, in this system water has to be regarded as an additive having a stabilizing function, as well as a solvent, and is, therefore, not part of the substance to be registered. The content of methanol is also listed both under impurities and additives. Methanol is regarded as an impurity when it's a residual starting material (0 - 3% (w/w)), as an additive when it's a stabilizer with a content between 4 and 15%. Thus, the substance is regarded as a mono-constituent substance, formaldehyde has a content in the range of 12 to 70% w/w and constituents besides formaldehyde and water have a concentration below 10%, except a few solutions which contains methanol at a content higher than 10%. Different manufacturing processes exist. They are based on the same chemical reaction but conditions (materials, pressure, temperature, catalysts) differ. The composition of aqueous solutions of formaldehyde from each process is not known in details.

7.4. Physico-chemical properties

Table 8

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Pure formaldehyde is a colourless gas, with a pungent and suffocating odour. Formaldehyde in aqueous solution (37 to 50 %) is a colourless liquid (at 20 °C and 1013 hPa) with a pungent odour. Cloudiness or opalescence in the formaldehyde solution is caused by polymer precipitation.

Vapour pressure	The vapour pressure of pure formaldehyde is ca 5176 - 5186 hPa at 25°C (gas). The vapour pressure of a 55% aqueous solution is 14 hPa at 20 °C and 92 hPa at 50 °C. The partial pressure of formaldehyde over water is 1.2 hPa and 1.3 hPa at 20 °C for 30 % and 50 % formaldehyde in aqueous solution respectively.
Water solubility	According to the available literature the water solubility of formaldehyde is ca 550 g/L at 20 °C.
Partition coefficient n-octanol/water (Log Kow)	0.35
Flammability	extremely flammable (gas) flammable liquid (aqueous solution >10% methanol) combustible liquid (aqueous solution ≤10% methanol)
Explosive properties	non explosive
Oxidising properties	no oxidising properties
Granulometry	not applicable
Stability in organic solvents and identity of relevant degradation products	According to the Ullmanns encyclopedia (2012), formaldehyde is not stable in polar solvents such as alcohols and amines, as it undergoes reaction with these compounds.
Dissociation constant	The pKa for formaldehyde is determined to range from 12.79-13.27 at temperatures ranging from 23-30°C.
Hazardous chemical reactions:	Risk of explosion in contact with: nitric acid, hydrogen peroxide, nitromethane, performic acid, peracetic acid, phenol, nitrogen dioxide (180 deg. C) The substance polymerize in contact with: alkalies, nitrides, polymerization initiators. The substance can react dangerously with:, strong oxidizing agents, potassium permanganate, magnesium carbonate, sodium hydroxide, perchloric acid + aniline, hydrochloric acid

7.5. Manufacture and uses

7.5.1. Quantities

Table 9

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☐ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☒ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

(ECHA dissemination site Registration dossier viewed on 26/02/19)

USES	Use(s)
Uses as intermediate	Manufacturing of Formaldehyde + aq. formaldehyds solutions Manufacturing of chemicals/resin/polymers Manufacturing of Formaldehyde + aq. formaldehyds solutions under strictly controlled conditions
Formulation	Formulation Formulation in industrial settings Formulation of a polymer Formulation of ink Formulation of Preparations Formulation or re-packing Grinding aid Impregnation of textiles Industrial use of formaldehyde based products Manufacturing of chemicals / resins / polymers Manufacturing of chemicals / resins / polymers under strictly controlled conditions Manufacturing of Formaldehyde + aq. formaldehyde solutions Not used, part of polymer Pack down of Bulk quantities Production of bonded fibers or fiber mats Production of bonded particulates (abrasive, casting, moulding) Production of firelighters Production of foams Production of impregnated paper Production of leather Production of paper Production of rubber Production of woodbased materials (panels, bricks, etc) Use of adhesives and coatings
Uses at industrial sites	End Use as monomer in an imported polymer Production of rubber Production of fertilizer granules Production of foams Production of woodbased materials (panels, bricks, etc) Production of impregnated paper Manufacturing of chemicals / resins / polymers production of bonded fibers or fiber mats Industrial use of formaldehyde based products Use of adhesives and coatings formaldehyde based products production of leather

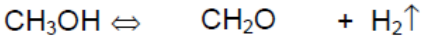
	production of paper Impregnation of textiles Production of firelighters Production of bonded particulates (abrasive, casting, moulding) Manufacturing of chemicals End use as monomer in an imported polymer Industrial use of the product Monomer in a polymer backbone Use as an intermediate, including use as a monomer Production of bonded particulates Manufacture of another substance Use as laboratory chemical Manufacturing resins Use as an adhesive Use as a solvent Application In Abrasive, Casting , Moulding formaldehyde based products intermediate Use as monomer in polymer synthesis outside of EU End use as monomer in an imported polymer
Uses by professional workers	This substance is used in the following products: adhesives and sealants, coating products, polymers and laboratory chemicals. This substance is used in the following areas: building & construction work. This substance is used for the manufacture of: textile, leather or fur, wood and wood products and pulp, paper and paper products. This substance is used in the following activities or processes at workplace: transfer of chemicals, mixing in open batch processes, laboratory work, roller or brushing applications, non-industrial spraying, treatment of articles by dipping and pouring and hot work operations with metals (e.g. welding, soldering, gouging, brazing, flame cutting).
Consumer Uses	adhesives and sealants, coating products, fillers, putties, plasters, modelling clay, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes,

	washing & cleaning products cosmetics and personal care products
Article service life	the low energy manipulation of substances bound in materials or articles, potentially closed industrial processing with minerals/metals at elevated temperature (e.g. smelters, furnaces, refineries, coke ovens), open transfer and processing with minerals/metals at elevated temperature, high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding) hot work operations with metals (e.g. welding, soldering, gouging, brazing, flame cutting). This substance can be found in complex articles, with no release intended: machinery, mechanical appliances, electrical/electronic products not covered by Waste Electrical and Electronic Equipment (WEEE) directive (e.g. large-scale stationary industrial tools). This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones) and wood (e.g. floors, furniture, toys).

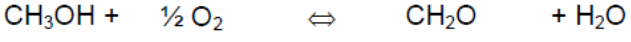
Manufacture of formaldehyde

Formaldehyde is technically produced as an aqueous solution by oxidative dehydrogenation of methanol with air via either a silver (for one half) or metal-oxide (the other half) catalyst process (Afsset, 2009; RPA/TNO, 2013):

- Partial conversion (via a silver catalyst heated from 600°C to 720°C):



- Total conversion (via a metal-oxide catalyst – iron, vanadium, molybdène) heated from 270°C to 380°C):



Formaldehyde production accounts for approximately 1/3 of global methanol demand.

In the EU, formaldehyde is usually manufactured, used and commercialised as an aqueous formaldehyde solution, known as **formol or formalin**, which usually does not contain more than 3% methanol or more than 10-15% depending on the source of information. Formaldehyde is commonly not produced in its pure form due to the fact that it is not stable in this form. Formal or Formalin is usually produced with 30% to 50% of

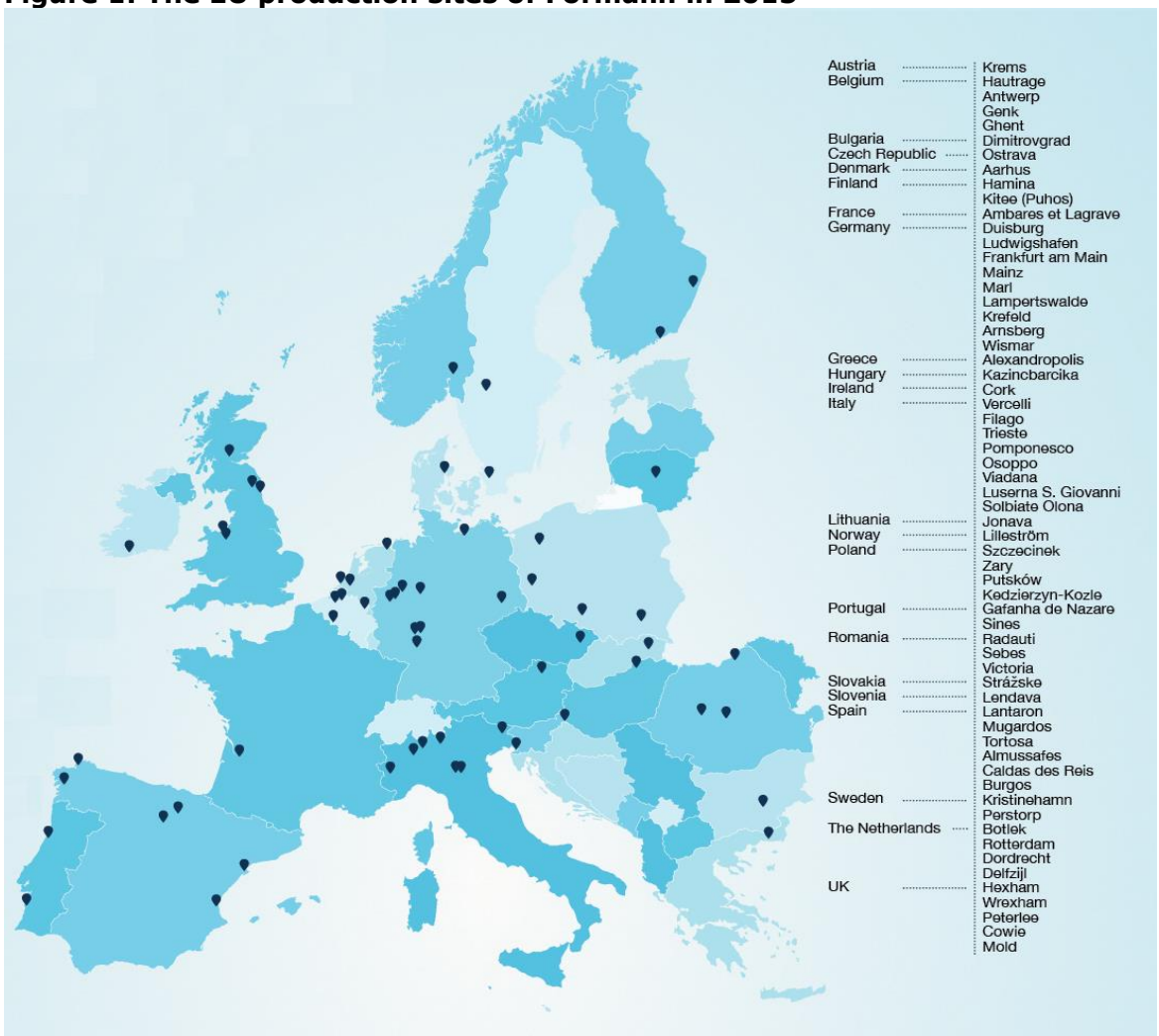
formaldehyde. **Available data on the production and use of formaldehyde provided below mainly refer to a 37% formaldehyde solution (unless otherwise stated).**

Formaldehyde is also commercialised in a polymerised or solid form (Afsset, 2009):

- **paraformaldehyde** (polymer) in the form of powder or white crystals with a concentration of 90% to 93% of formaldehyde and up to 10% water;
- **trioxane** (trimer) in the form of solid crystal.

In 2010, 29 million tonnes of formalin (37% formaldehyde) were produced globally, of which Europe accounted for 23% (6.7 million tonnes) as the second largest producer after Asia (50%). The world production capacity of Formalin is 40 million tonnes per year of which Europe represents around 25% with a production capacity of 9.5 million tonnes per year (quoted in RPA/TNO, 2013). In 2013, ICF reported an EU production of over 7 million tonnes of Formalin (ICF, 2013). In 2009, Formacare reported a production of formaldehyde of 3.6 million tonnes (100% formaldehyde) be it around 30% of global production. The Figure[5] below presents the location of the 61 production sites of formaldehyde in the EU in 2015 (22 Member States in 28).

Figure 1: The EU production sites of Formalin in 2015



[5] Source: http://www.formacare.org/about-formaldehyde/eu-market/, accessed in June 2016

Within Europe, Germany is the biggest manufacturer of Formalin with a production of 2.2 million tonnes per year in 2010 which stands respectively for 33% of European production capacity and 7.5% of the global production capacity. Germany is followed by Italy, Spain, the Netherlands and the UK (Unpublished report, 2007; ICF, 2013).

Table 10. Main Manufacturers and production volumes of Formalin in Europe in 2013

Name	Annual production volume, thousand tonnes
Dynea, the Netherlands	720
BASF, Germany	650
Perstorp Formox, the Netherlands	550
Degussa, Germany	519
Ercros, Spain	400
Hexion, the Netherlands - Germany	390
Bayer, Germany	271
Sadepan Chimica, Italy	250
Ticona Polymerwerke, Germany	238
Dynochem, Great Britain	225
Sonae, Portugal	220
Caldic Chemie, the Netherlands	215
Krems Chemie, Austria	175
Chimica Pomponesco, Italy	160
Perstorp, Italy	140
Polioli, Italy	140
Osterreichische Hiag-Werke, Austria	125
Forestales Atlanticos, Spain	120
Nordalim, Denmark	115
Akzo Nobel, Sweden	110
TOTAL	**5.7 million tonnes**

Source : Danish EPA, 2014 (information retrieved from www.export.by, 2013)

Table 11. Production capacity of Formalin in Europe in 2010

Country	Production volume (thousand tonnes)	Production capacity (thousand tonnes)
Austria	140	175
Belgium	232	290
Bulgaria	24	30
Denmark	92	115
Finland	128	160
France	44	54
Germany	1,716	2,145
Hungary	48	60
Ireland	64	80
Italy	736	919
Lithuania	86	107
Portugal	244	305
Spain	660	825
Sweden	432	540
The Netherlands	760	950
UK	372	465
TOTAL	**5.7 million tonnes***	**7.2 million tonnes***

Source : RPA/TNO, 2013
*sums not indicated in RPA/TNO, 2013

Uses of formaldehyde

Formaldehyde is a widespread use substance. It is produced for a very wide range of uses and applications from industrial synthesis of chemicals to general public applications.

At industrial and professional level, formaldehyde is used as :

- An intermediate in chemical synthesis, such as the synthesis of:
  - methylene dianiline (MDA)
  - diphenylmethane diisocyanate (MDI)
  - hexamethylenetetraamine (HTMA - hexamine)
  - trimethylol propane
  - neopentylglycol
  - pentarythritol (for the production of alkyd resins and neopolyol esthers)
  - butanediol (BDO)
  - acetylenic agents
- A starting material in the chemical industry for the production of:
  - condensed resins such as:
    - Urea-Formaldehyde (UF) resins
    - Melamine-Formaldehyde (MF) resins
    - Phenol-Formaldehyde (PF) resins
  - Polyacetal resins (polyoxymethylene – POM)
  - Paraformaldehyde (PFA), the smallest polyoxymethylene
  - Paper for graphism, hygienic, specific applications
  - Textile including printing inks, dyes and textile finishing products
- A reagent and bactericidal agent used in healthcare applications such as tissue preservation, embalming fluids in autopsy rooms and pathology departments, disinfectant in operating rooms, vaccines, animal medicines, etc.
- A preservative, biocidal and cleaning agent in food applications
- A biocidal in germicides, bactericides and fungicides as well as an ingredient in fertilisers in agriculture and non-agricultural sector

In consumers/general public applications, formaldehyde is used (Afsset, 2009):

- As a preservative and biocidal agent in detergent, disinfectant and cleaning agent
- As a preservative in cosmetics [and nail hardeners[6]]
- In building and insulating material (such as UF or PF foam insulation)[7]
- In wood-based panels[8]
- As a binding agent in paints and lacquers
- As a binding agent in adhesives
- In human food (food additive and processing aid)
- In vaccines and medicines

The ECHA dissemination website gives product categories and sectors of use of formaldehyde, summarised in the Table below:

[6] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_164.pdf

[7] In this product, formaldehyde is not present as such but as a formaldehyde-based polymer (resin or glue)

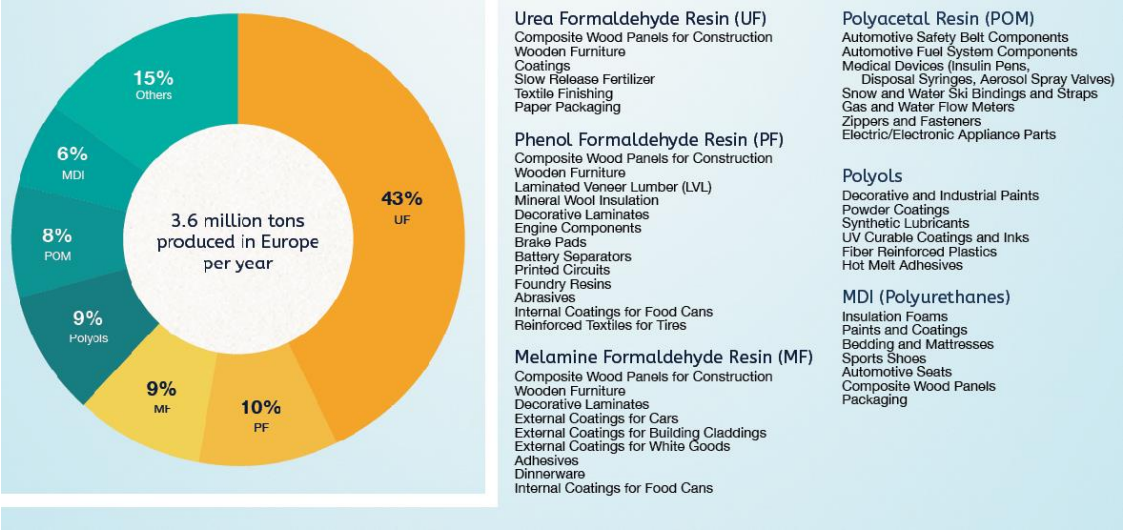
[8] In this product, formaldehyde is not present as such but as a formaldehyde-based polymer (resin or glue)

Table 12. Product categories and sectors of use of formaldehyde (ECHA dissemination website)

Product categories	Adhesives and sealants, coating products, cosmetics and personal care products, washing & cleaning products, fuels, biocides, polishes and waxes, polymers, fillers, putties, plasters, modelling clay and inks and toners
Sectors of use	Formulation of mixtures and/or re-packaging and building & construction work. Manufacture of chemicals, plastic products, textile, leather or fur, pulp, paper and paper products, mineral products (e.g. plasters, cement) and rubber products

The EU vs. world consumptions of formaldehyde per use are represented in the figures below.

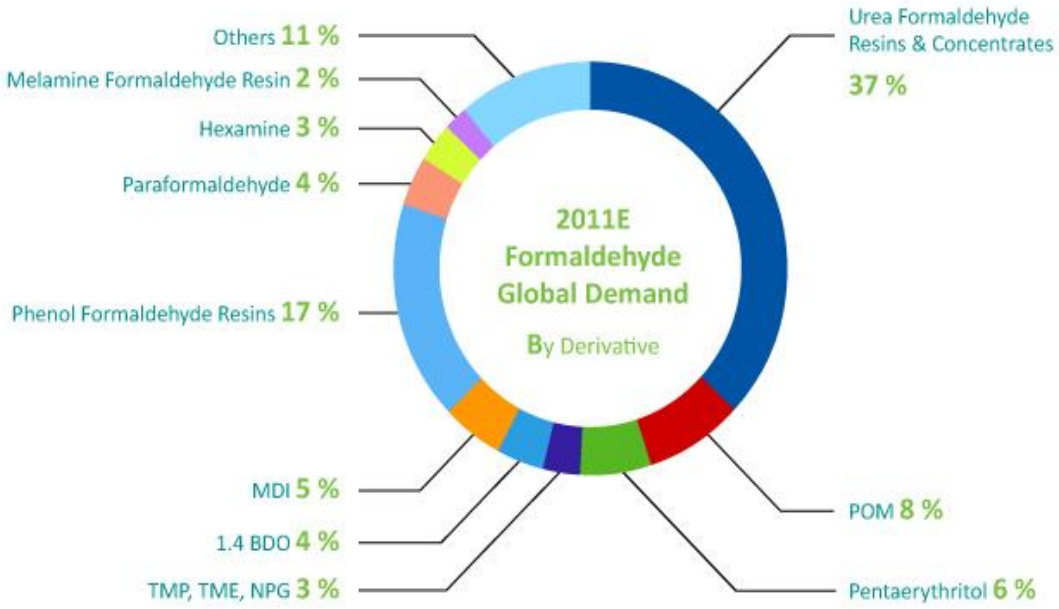
Figure 2. EU consumption of formaldehyde (100%) per use



Source: Formacare website (June 2015)

Figure 3. World consumption of formaldehyde per derivative in 2011[9]

[9] Source: http://www.formacare.org/about-formaldehyde, accessed in June 2016



The flow diagram below provides an overview of the uses and the supply chain for formaldehyde (inspired from ICF 2013, updated and completed).

A detailed analysis of uses is provided in the RMOA assessment (the conclusion when available will be published in the public activities coordination tool (PACT)).

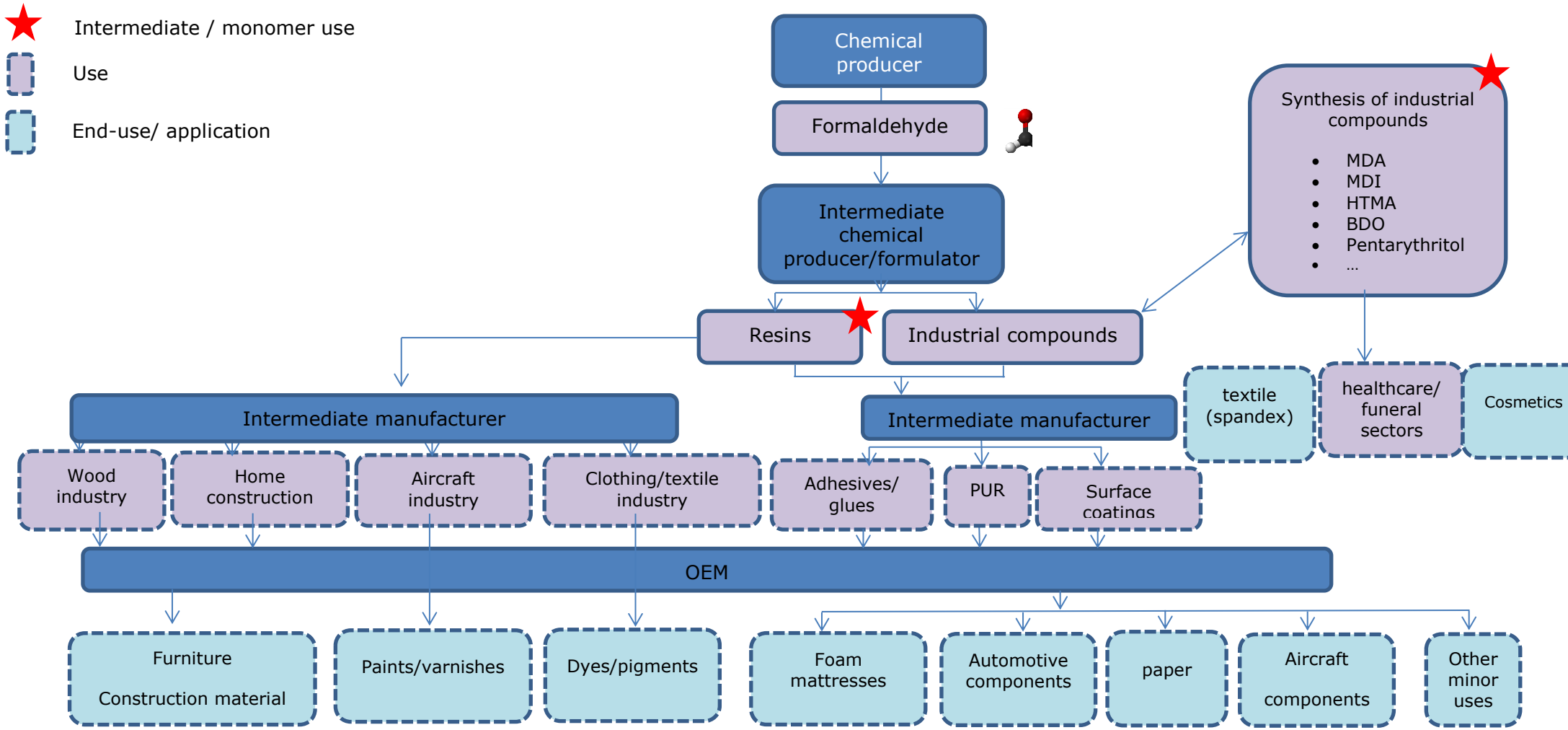


Figure 4. Overview of the uses of Formaldehyde and the corresponding supply chain

PUR: manufacturing of polyurethane (PUR) products

OEM: Original Equipment Manufacturer

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

While the Substance Evaluation process was ongoing, harmonized classification for formaldehyde was revised. Following the publication of the 6th Adaptation to Technical Progress (ATP) to the classification, labelling and packaging of substances and mixtures (CLP) Regulation on 6th June 2014 (Regulation 605/2014), formaldehyde was reclassified to carcinogenic category 1B and mutagen category 2. This new classification entered into force on 1 April 2015. The complete harmonised classification according to Annex VI of CLP regulation for formaldehyde is presented in **Table 13**.

It is remarked that classification for serious damage to eyes is covered by Skin Corr 1B and H314 (Causes severe skin burns and eye damage).

Table 13

HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008)							
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Spec. Conc. Limits, M-factors**	**Notes**
				Hazard Class and Category Codes	**Hazard statement codes**		
605-001-00-5	Formaldehyde …%	200-001-8	50-00-0	Acute Tox. 3 * Acute Tox. 3* Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 Carc. 1B Muta 2	H331 H311 H301 H314 H317 H350 H341	Skin Irrit. 2; H315 : 5% ≤ C < 25% Eye Irrit. 2; H319: 5% ≤ C < 25% Skin Corr. 1B; H314: C ≥ 25% STOT SE 3; H335: C ≥ 5% Skin Sens. 1; H317: C ≥ 0,2%	B, D

7.6.2. Self-classification

- In the registration(s)*:*

The following adapted classification is presented: Acute Tox 2 – H330

- The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory*:*

  - Acute Tox. 2 - H 330
  - Acute Tox. 4; - H302
  - Aquatic Chronic 2; - H411
  - Carc. 1A; - H350
  - Carc. 2; - H351
  - Eye Dam. 1; - H318
  - Flam. Gas 1 - H220
  - Met. Corr. 1 – H290
  - Resp. Sens. 1 – H 334
  - Resp. Sens. 1A – H317
  - Skin Corr. 1 – H 314

- Skin Corr. 1A; - H314
- Skin Corr. 1A; H 314
- Skin Corr. 1C; H 314
- Skin Sens. 1A; H 317
- STOT RE 1 – H372
- STOT SE 1 – H370
- STOT SE 3; - H335

7.7. Environmental fate properties

Not evaluated.

7.8. Environmental hazard assessment

Not evaluated.

7.9. Human Health hazard assessment

Data and their analysis are summarised below in section 7.9.1 to 7.9.9.

7.9.1. Toxicokinetics

Formaldehyde is a normal endogenous metabolite and has been found in all tissues investigated. Formaldehyde reacts at the site of first contact in the body and/or is eliminated rapidly as formic acid in the urine or as CO_2 in the expired air or it enters the carbon-1 pool in the body. Dermal absorption should differentiate between penetration through the skin possibly leading to systemic effects and penetration into the skin possibly leading to local effects. For monkeys penetration through the skin was 4% and through + into skin 15%. In rats and guinea pigs, ca. 40% of the applied formaldehyde is absorbed via the skin. In *in vitro* experiments using guinea pig skin the percutaneous absorption rate was ca. 30% after 1 h of exposure. The following values are further considered for dermal absorption: 4% for penetration through the skin possibly leading to systemic effects; 15% for penetration through and into the skin possibly leading to local effects.

In humans 76% absorption was reported after inhalation exposure for the nasal passages (90% in rats) and almost complete absorption in the total respiratory tract of humans and rats (Overton et al., 2001). Therefore 100% systemic absorption is assumed for respiratory tract of rats and humans. Almost complete absorption was reported after oral exposure.

Formaldehyde is rapidly metabolised (t1/2 ~ 1 min) by formaldehyde dehydrogenase (FAD). Since toxicity is a consequence of exposure to a very reactive parent compound that is not removed from the site of application allometric scaling is not appropriate (ECHA, 2012). FAD is highly conserved and is found in all tissues and species investigated as the most important scavenger for the highly toxic endogenous formaldehyde. In several investigations no polymorphism of FAD has been detected in humans.

7.9.2. Acute toxicity and Corrosion/Irritation

Acute Toxicity

The range of oral LD_{50} values in male rats was 460-832 mg/kg bw (2-4% formaldehyde solution); the mean LD_{50} value of five independent experiments was 640 mg/kg bw. The most sensitive reliable value is an oral LD_{50} of 460 mg/kg bw.

In acute inhalation studies in rats the LC_{50} (30 min) was 1000 mg/m³ and the LC_{50} (4 h) was 588 mg/m³ = 490 ppm. Inhalation exposure resulted in local effects.

No valid data are available on acute dermal toxicity, however, formaldehyde has corrosive properties.

No further action is required for this endpoint under SEv.

Skin irritation

Formaldehyde is classified with Skin Corr 1B and H314 (Causes severe skin burns and eye damage).

There is one key study on skin irritation in rabbit, supporting studies with rat and additional information from the skin sensitization in animals and humans. According to the registrants, irritant effects are expected at concentrations > 3%. This conclusion was confirmed by a recent study on microvascular leakage of rat skin, where skin damage was demonstrated at concentrations >= 2.5% formaldehyde.

According to the eMSCA, the key study on rabbits has significant deviations from OECD 404 concerning exposure time and application regime. However, the weight of evidence leads to the conclusion that a solution of 40% formalin is corrosive to skin (see 7.6 Classification). The eMSCA does not have any remaining concerns on skin irritation and skin corrosion and no further data were requested.

Eye irritation

Formaldehyde is classified with Skin Corr 1B and H314 (Causes severe skin burns and eye damage).

No data according to current guidelines is available. Studies on skin irritation/corrosion brought evidence for corrosive properties (no testing for eye irritation required). Supportive, less reliable eye irritation studies confirm the corrosive properties to eye.

According to the registrant, corrosive properties of formaldehyde solution in the eye at concentration in the range of 7% are to be expected.

The weight of evidence leads to the conclusion that formaldehyde is to be regarded as substance causing serious eye damage (see 7.6). The eMSCA does not have any remaining concerns on eye damage and no further data were requested.

Irritation in humans exposed to gaseous formaldehyde

There are numerous formaldehyde human sensory irritation studies available. Two recent clinical studies with volunteers are identified as key studies by the registrants: Lang (2007) and Mueller (2013), with the most sensitive endpoint being sensory eye irritation, measured by the blinking frequency. According to the eMSCA both key studies are of equal value and reliability. Concentration levels of 0.5 ppm formaldehyde without peaks, and 0.3

ppm with peaks of 0.6 ppm were considered to be NOAECs in the Lang (2007) study, based on subjective and objective sensory eye irritation. The results in the study from Mueller (2013) (NOAEL was 0.7 ppm without peak exposure and 0.4 ppm with 0.8 ppm peaks) are supporting the findings from Lang (2007). Moreover, the difference in NOAEC values is minimal.

Based on the available data, formaldehyde is considered to be corrosive to skin and cause serious eye damage, in line with the current harmonised classification and labelling.

As for (sensory) irritation of humans exposed to gaseous formaldehyde, there is enough information to support DNEL derivation for this endpoint.

No further action is required for this endpoint under SEv.

7.9.3. Sensitisation

There is sufficient evidence for sensitising properties of formaldehyde in the guinea pig maximisation test (GPMT) and in the mouse local lymph node assay (LLNA). Formaldehyde is also a dermal allergen in humans. Although rare, anaphylaxis has been documented in case reports. Animal studies do not indicate that formaldehyde may induce sensitisation to the respiratory tract. A very limited number of case reports have been published on formaldehyde-related asthma but these data do not provide sufficient evidence that formaldehyde should be considered a risk factor for respiratory tract sensitisation. Recently the data on skin and respiratory tract sensitisation by formaldehyde have been comprehensively reviewed by the German MAK commission (MAK, 2010). With regard to skin sensitisation MAK (2010) concluded that allergic contact dermatitis is relatively frequently observed in patients by diagnostic patch testing. In addition, many experimental animal studies gave positive results for skin sensitisation. Formaldehyde has a harmonised classification Skin Sens. 1 (H317) with a specific concentration limit of 0.2%.

As asthma related to formaldehyde is concerned, MAK (2010) concluded that the allergological findings do not provide a consistent pattern. In inhalation challenge tests generally immediate reactions were observed, 2-phase or late reactions were rare. A differentiation against irritation was difficult and specific IgE antibodies, if found, mostly did not correlate with the respiratory symptoms. Overall, a relationship of respiratory symptoms with formaldehyde was sufficiently documented only in few cases. The small number of reliable findings in comparison to the broad exposure potential would not warrant to classify formaldehyde as a respiratory sensitiser according to the criteria of the MAK commission.

Overall, specialised studies with experimental animals did not provide sufficient evidence for a formaldehyde-induced respiratory allergy. In general, the results in human studies did not provide clear evidence for a formaldehyde-induced respiratory allergy. Reported symptoms in case reports might also be related to irritant effects.

No further action is required for this endpoint under SEv.

7.9.4. Repeated dose toxicity

In experimental studies, formaldehyde induces toxic effects only at the site of first contact after oral, dermal or inhalation exposure. General signs of toxicity occur secondary to these local lesions. In chronic drinking water studies in rats local effects in the forestomach and stomach were induced, the NOAEC is 0.020- 0.026% formaldehyde in drinking water. For systemic effects the NOAEL is ≥ 82 mg/kg bw/day in males and 109 mg/kg bw/day in females.

Studies on dermal repeated dose toxicity in compliance with current Guidelines are not available.

Local effects in the upper respiratory tract were induced after repeated inhalation exposure in experimental animals. The most sensitive site in rodents and monkeys is the respiratory epithelium in the anterior part of the nasal cavity. At higher dose levels also the olfactory epithelium, larynx or trachea were affected, especially in monkeys. Rats are more sensitive than mice or hamsters. The LOAEC is 2 ppm in rats (2.4 mg/m³), 3 ppm in monkeys and 6 ppm in mice. The overall NOAEC in experimental animals for local effects is 1 ppm (1.2 mg/m³). The NOAEC for systemic effects in long-term inhalation studies in rats and mice is 15 ppm.

As mentioned above the most sensitive endpoint in humans is sensory eye irritation by exposure to formaldehyde gas. In the most relevant controlled study (Lang et al., 2008) with human volunteers the NOAEC was 0.5 ppm or 0.6 mg/m³ at constant exposure conditions and 0.3 ppm with peaks of 0.6 ppm. These results were confirmed by the results of a recent study (Muller et al., 2010).

No further action is required for this endpoint under SEv.

7.9.5. Mutagenicity

Formaldehyde is classified Muta 2 – H341.

In vivo at the site of contact in somatic cells, positive evidence in mutagenicity tests are available from induction of chromosomal aberrations in rats by inhalation at high dose (Dallas 1992) and of micronuclei in rats in the GI tract by oral route (Migliore 1989).

These positive data are further supported by:

- in vitro positive results in numerous genotoxicity and mutagenicity tests

- in vivo induction of DNA adducts and DNA protein cross links at the site of contact

- indications of consistent increases in micronuclei frequency in humans at the site of contact.

No further action is required for this endpoint under SEv.

7.9.6. Carcinogenicity

Formaldehyde is classified Carc 1B – H350.

In a valid chronic oral study local effects were induced in the forestomach and stomach of rats at a concentration of 0.19% (NOAEC 0.02%) but no carcinogenic activity. In another drinking water study, local carcinogenic effects were shown in rats, however, the validity of the study is limited and the histopathological criteria for the papillomas described are unclear. Overall, no convincing evidence of a carcinogenic effect of formaldehyde via oral route is available.

Clear local carcinogenic effects were reported in the nasal cavity of rats after long-term inhalation exposure to =/> 6ppm. The carcinogenicity of formaldehyde is well established in rats by inhalation with the induction of tumours at the site of contact. The results from

epidemiological studies suggest an increased risk of cancer: there is evidence from the National cancer institute (NCI) cohort and from several case-control studies that formaldehyde may induce nasopharyngeal cancer (NPC).

Based on experimental data, the biological plausibility of the induction of nasopharyngeal carcinomas in humans exposed to formaldehyde highly supports the epidemiological evidence obtained from the NCI cohort and from several case-control studies.

A correlation between formaldehyde exposure and leukaemia, especially myeloid leukaemia, was seen in some available studies. According the current understanding, a risk for potential induction of haemopoietic cancers by formaldehyde may be regarded unlikely in humans at doses that do not saturate local detoxification at the site of first contact. This is supported by results from long-term studies in rats after inhalation exposure, which provide no firm indication that formaldehyde is able to induce neoplasm of the haemotopoeitic system in animals.

Based on the current knowledge, it is therefore concluded that risk assessment based on the local carcinogenic effects of formaldehyde is considered protective for potential systemic effects.

Uncertainties related to leukaemia induction is linked to a lack of plausibility of a potential mechanism of action.

However, eMSCA consider that these uncertainties cannot be addressed by a request of a further study in the context of the Evaluation process under REACH. In particular, it is noted that carcinogenicity studies by inhalation have been conducted and these studies did not highlight any significant increase of leukemia in treated animals. The request of a carcinogenicity study by oral route does not seem appropriate as it is not a relevant exposure route for formaldehyde.

No further action is required for this endpoint under SEv.

7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

There is no evidence for effects on reproductive organs in experimental animals after oral or inhalation exposure. There is no evidence for adverse effects of formaldehyde on embryo and foetal development even at dose levels leading to local maternal toxicity.

No further action is required for this endpoint under SEv.

7.9.8. Other effects

Neurotoxicity

Data on neurotoxicity in rodents are available. Effects on the hypothalamus, pituitary gland and adrenals as well as neuroimmunological effects were detected in mice at low exposure levels of ≥ 0.1 ppm in inhalation studies. In young rats learning and memory were impaired after repeated inhalation exposure to 0.1 ppm formaldehyde. Since these effects might be related to olfactory stress, (unrelated to systemic toxicity) the relevance of these results for humans is questionable. Mice and rats are macrosmatics and human are microsmatics.

Neuropathological effects in the limbic system of rats were described after repeated inhalation exposure to dose levels ≥ 6 ppm. In none of these studies was the likely

degeneration of the olfactory epithelium investigated. Since the olfactory system has direct connection to the limbic system, these effects are considered not to be systemic effects but secondary to local effects in the nasal cavity (site of 1st contact).

Immunotoxicity

No specific conclusion can be drawn based on limited data.

No further action is required for these endpoints under SEv.

7.9.9. Hazard assessment of physico-chemical properties

The eMSCA notes that some aqueous solutions of formaldehyde contains methanol in concentration ≥ 10% and are therefore classified as flammable. The flammability hazard is adequately considered in the updated CSR, when relevant.

No further action is required for these endpoints under SEv.

7.9.10. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

Derivation of workers DNELs

DNELs via dermal route

Due to the corrosive and sensitising properties of formaldehyde, the establishment of dermal DNEL and dermal quantitative risk assessment were not considered to be relevant. Risk needs to be qualitatively assessed based on consideration of relevant exposure situations and suitability of PPE (see the risk characterisation section 7.13.1).

DNELs by inhalation

Local long-term DNEL for the inhalation route

ANSES considers that the carcinogenic mode of action of formaldehyde relies on a serie of key events above a threshold. In animals, nasal tumours are only observed at doses producing chronic irritation as evidenced by the accompanying inflammatory, hyperplastic and metaplastic responses. *In vitro*, formaldehyde is a genotoxic agent for high doses only. Epidemiological data shows formaldehyde genotoxicity is observed at the site of contact. A consistent database provides evidence that the mechanism of induction of local tumours is driven by regenerative proliferation that may secondarily amplify the high-dose genotoxic effects of formaldehyde. Prevention of irritant effects of formaldehyde is therefore considered protective of its carcinogenic effects. The dose-response relation for tumour incidence is essentially dependent on cell proliferation which is not observed at the low dose range. For formaldehyde, the practical threshold for cytotoxicity is considered to be protective for its genotoxic and carcinogenic effects.

Sensory irritation occurs at lower concentrations than cytotoxic irritation. The mode of action relies on the stimulation of trigeminal nerves leading to clinical observations such as eye or nose irritation. Thus, sensory irritation observed in humans is considered to provide a sufficient margin of safety regarding intraspecific variability for the onset of

irritation-induced cytotoxicity and cell proliferation inducing carcinogenicity in humans after long-term inhalation exposure (see below).

The most relevant controlled studies of Lang *et al.* (2008) and Mueller *et al.* (2013) took into consideration objective signs of sensory irritation (eye blinking rate, nasal resistance and flow), influence of personality factors and confounding by odor (Lang study). According to the identification of objective signs of ocular and nasal sensory irritation, which are the most sensitive effects, the NOAEC is set at 0.3 ppm and is chosen for the derivation of long-term DNEL. No AF is applied as epidemiological data show that formaldehyde vulnerable occupational subpopulation were already considered in the Lang and Mueller studies. Besides, sensory irritation is a precursor key event providing a margin of safety for the onset of more severe irritative effects of formaldehyde.

The Worker long-term DNEL for inhalation is 0.3 ppm (0.37 mg/m^3).

A limit of 0.3 ppm would prevent sensory irritation in occupationally exposed individuals but will not protect from 'nuisance' at the workplace cause by subjective symptoms of irritation and odor" since data from Lang *et al.* (2008) and Mueller *et al.* (2013) support the occurrence of subjective annoyance at equivalent concentrations.

Local short-term DNEL for the inhalation route

Results available from human studies indicates that eye irritation is the most sensitive effect induced by an acute exposure to formaldehyde. It occurs at concentrations below concentrations inducing respiratory irritation. Eye irritation is therefore the most sensitive endpoint retained as the critical effect for DNEL derivation by inhalation.

Lang and Mueller studies design comprise exposition to formaldehyde during 4 hours with a serie of peaks of exposure, considered as realistic exposure conditions at work. Objective tests for eye irritation were implemented measuring eye blinking rate or conjunctival redness. The NOAEC for eye irritation was thus set at 0.6 ppm. No assessment factor was applied for the same reason as mentioned above.

The Worker short-term DNEL for inhalation considered in the RMOA is 0.6 ppm (0.74 mg/m^3).

The establishment of DNELs for systemic effects by inhalation is not considered needed as systemic effects by inhalation are covered by the worker-DNEL for local effects by inhalation. Indeed, local irritant effects are expected to occur before the occurrence of systemic effects.

Table 14 – Critical DNELs

CRITICAL DNELS					
Endpoint of concern	**Type of effect**	**Critical studies**	**Corrected dose descriptor(s) (NOAEC)**	**DNEL**	**Justification/ Remarks**
Worker long-term DNEL for inhalation	Eye irritation	Lang 2008 Mueller 2013	0.3 ppm	0.3 ppm	

Worker short-term DNEL for inhalation	Eye irritation	Lang 2008 Mueller 2013	0.6 ppm	0.6 ppm	

Derivation of consumer DNELs

The DNEL for inhalation, local long term effects, is the most critical DNEL for general population (consumer). The registrants derived a DNEL of 0.3 ppm applicable for long-term local exposure via inhalation by workers and applied an assessment factor of 3 to extrapolate to the indoor situation for the general population. This resulted in DNEL of 0.1 ppm. The registrant took also into account that using a comparable dataset, WHO proposed an indoor exposure limit of 100 µg/m³ (24 h/d) that prevents sensory irritation and cancer in the general population. This value is finally proposed by registrants as DNEL general population chronic inhalation local: 100 µg/m³ or 0.083 ppm.

Taking into account that the DNEL of 100 µg/m³ (0.081 ppm) proposed by the Registrants was sufficient to substantiate the concern, the eMSCA decided to use this DNEL value for risk characterization.

7.9.11. Conclusions of the human health hazard assessment and related classification and labelling

Human health hazard assessment is summarised in sections 7.9.1 to 7.9.10 above. No need for revision of the existing harmonised classification is identified.

7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

7.11. PBT and VPVB assessment

Not evaluated.

7.12. Exposure assessment

7.12.1. Human health

Worker

The assessment of worker exposure is presented and discussed in section 7.13 below.

Consumer

A Decision (ECHA 2015) with a request for information was sent to the Registrants on 6 October 2015. The Decision required Registrants to provide a review of literature data on the emission rates (in µg/m^2/h), comprising time-dependency (where available) for the major sources and their relative contribution to the total indoor air concentration of

formaldehyde. Registrants were asked to update their registration dossiers with the required information before 13 October 2017.

For further detail, see Decision on formaldehyde dated 6 October 2015 (ECHA, 2015).

Following the update of the registration dossier in October 2017 new exposure information was provided. It is noted that the registrants fullfilled the requirements as set out in the Decision. A comprehensive report was submitted as an attachment to the registration dossier (Salthammer 2017).

This report contains data on formaldehyde emission from the following sources:

- Indoor chemistry: formaldehyde concentrations as determined in test chamber experiments in the presence of ozone (carpet, gas phase, latex paint, air freshener, painted wooden board, cleaning agent and different materials)
- Burning of candles
- Incense burning
- Consumption of conventional and electronic cigarettes
- Cooking and cooking related activities
- Ethanol fireplaces
- Miscellaneous products (cleaning agents, cosmetics)
- Wood combustion
- Air cleaning devices and paints
- Textiles
- Carpet
- Wallcoverings
- Surface coatings
- Solid wood
- Raw wood-based materials
- Furniture
- Laminate
- Windows and doors
- Mineral wool

This report contains statistical analyses of the emissions distributions, where possible. For some sources (ethanol fireplaces, for example) emissions were calculated from maximum concentrations. For relevant sources (wood based panels and furniture), the ageing effect was taken into account. Sink effect, i.e. interaction between gas phase and surfaces by adsorption and absorption, was taken into account in all continuous emission sources. The influence of wood based panels' coverings was described.

A thoughtful analysis of the single sources contributions to the general indoor air concentration was given. An air concentration of formaldehyde modelled for a reference room, taking into account several sources forms a very good overview and allows comparison of the contribution of sources. To make comparison more transparat, sources have been divided in classes depending on their contribution to the total Reference Room concentration for 50-P and 95-P: >10 µg/m^3, 10 – 50 µg/m^3, 50 – 100 µg/m^3 and >100 µg/m^3.

Table 15: Simulated reference room concentrations for different emission sources

	Product	25-P [µg/m³]	50-P [µg/m³]	75-P [µg/m³]	90-P [µg/m³]	95-P [µg/m³]	Remark
Temporary sources	Burning candles	8.5	**12.3**	17.6	24.3	**29.6**	1 item
	Burning incense	12.0	**21.0**	30.0	35.4	**37.2**	1 item
	Cooking	33.2	**44.2**	59.0	76.0	**88.7**	
	Ethanol fireplaces	77.8	**152.2**	244.6	347.3	**419.5**	1 item
	Wood combustion	15.7	**26.5**	37.3	43.7	**45.8**	
Permanent sources	Air cleaning devices	7.7	**13.5**	19.2	22.7	**23.8**	1 item
	Outdoor air	2.6	**4.3**	7.2	11.3	**14.9**	
	Indoor chemistry	1.7	**2.6**	3.9	5.8	**7.3**	
	Textiles	2.6	**3.6**	5.2	7.0	**8.4**	L = 1 m^2/m^3
	Solid wood	5.4	**7.5**	10.3	13.6	**16.0**	L = 1 m^2/m^3
	Flooring (laminate)	4.0	**6.5**	10.9	16.5	**21.3**	L = 0.4 m^2/m^3
	Flooring (carpet)	1.9	**3.0**	4.6	6.7	**8.5**	L = 0.4 m^2/m^3
	Wall (covered PB)	27.0	**38.3**	53.4	72.2	**86.0**	L = 1 m^2/m^3
	Wall (covered OSB)	12.3	**20.2**	31.5	46.2	**57.5**	L = 1 m^2/m^3
	Wall (covered MW)	5.0	**8.6**	14.7	24.0	**31.9**	L = 1 m^2/m^3
	Wall (surface coating)	2.9	**4.4**	6.6	9.4	**11.7**	L = 1 m^2/m^3
	Wall (wallcovering)	0.5	**1.0**	1.8	3.0	**4.2**	L = 1 m^2/m^3
	Doors	0.9	**1.7**	3.6	6.9	**10.3**	L = 0.05 m^2/m^3
	Windows	2.0	**2.0**	2.0	2.0	**2.0**	L = 0.05 m^2/m^3
	Furniture	20.5	**38.1**	66.3	105.3	**148.8**	L = 1 m^2/m^3
	Miscellaneous	2.0	**3.0**	4.0	4.6	**4.8**	1 item

PB = Particleboard, OSB = Oriented strand board, MW = Mineral wool

The final reference room concentration was modelled based only on continuous sources. Temporary sources, such a combustion sources (fireplaces, cooking) were not included. Extended discussion on sources, their contributions and modulating factors (aging, sink and covering) was provided.

The eMSCA concluded that sufficient information has been provided. Supplied data have been evaluated and the main sources were identified following the approach described below.

For the purposes of the single source contribution comparison, 95-P values have been chosen by the eMSCA. This choice has been made to assure that the worst case scenarios have been taken into account. The eMSCA is aware that some of 95-P values are outliners. For example from 21 samples measured for furniture, three samples had five to ten times higher emissions than the others. Using 95-P values assures protection of consumers exposed also to the outliners.

As the goal of current evaluation was the identification of main formaldehyde sources, the eMSCA focused on the sources with the highest emissions. Other sources (adding to the Reference Room concentration around 10 µg/m³ and less (95-P),expert judgement) that are not discussed here in this evaluation but may still be of relevance are for any follow-up action are:

- Indoor chemistry
- Textiles
- Solid wood
- Wallpapers (paper, textile, vinyl, acrylic)
- Miscellaneous products (cleaning agents, cosmetics)
- Surface coatings (paints and lacquers)
- Flooring (carpet)
- Doors
- Windows

Mineral wool is used as insulation; it is always covered by other building materials. Therefore, it was not included as a relevant source for emitting formaldehyde. Smoking of conventional and electronic cigarettes are considered outside the scope.

The results show that wood based panels and furniture are the main formaldehyde continuous emission sources. Based on the information provided by the registrant, emissions from these sources vary significantly within each category and between categories.

For the temporary sources the highest emissions were measured for combustion sources, such as cooking, ethanol fire places, wood combustion, incense and candles.

Wood based panels

There was not enough data in the initial registration dossiers on formaldehyde emissions from wood based panels, certainly not for a proper assessment of emissions from different types of panels and influence of the additional panels processing/finishing.

In the report from the registrants (Salthammer 2017) submitted to fulfil the requests as formulated in ECHA's Decision (ECHA, 2015), emission data for different types of panels were supplied together with the detailed explanation on the influence of covering with different types of material. Covering (with paint, primer, paper, wallpaper, melamine paper) of the wood based panels limits formaldehyde emission significantly. Wood based panels used indoors may be covered/sealed on the front, on the front and the back, or on responsible for the most of the emission.

Table 16: Formaldehyde concentrations in the test chamber under the conditions of pfEN 16516 (T = 23°C, RH = 50%, ACH = 0.5 h^{-1}, L = 1 m^2/m^3) (adapted from Salthammer 2017)

Construction	**C [µg/m³]**
Particleboard	160
Particleboard + gypsum plasterboard	120
Particleboard + gypsum plasterboard + woodchip wallpaper + paint	98.26
Particleboard + gypsum plasterboard + vinyl wallpaper	61.41
Particleboard + diffusion barrier film + gypsum plasterboard + vinyl wallpaper	24.56

ppm to µg/m³ recalculated with http://www.aresok.org/npg/nioshdbs/calc.htm, using Mw = 30.03.

An additional document supplied to ECHA by the registrants, "Call for evidence" report, contains important information on different methods of formaldehyde emission measurements from wood bassed panels. See for details Chapter 8, Evaluation Report.

Concluding, the provided data were sufficient to identify wood based panels as a major continuous formaldehyde source. Follow-up actions are proposed as indicated in Part A.

Furniture

Furniture is reported as a separate category of formaldehyde emission source. However, in fact furniture is one of or a combination of other formaldehyde sources: solid wood, textile and wood based panels. The question may arise, if an article with this variable composition should be treated as one emission source. Emission rate from textiles was considered low (<0.4 - 5 µg/m^2h (Aldag 2017)), therefore they can be left out. Specific Emission Rates from solid wood were considered low as well (3 -7 µg/m^2h, Risholm-Sundmann et al. (2007), Böhm et al. (2012), Meyer and Boehme (1997)). For wood based panels emissions are discussed separately.

Laminate flooring

Laminate is a multi-layer flooring product. First, the uppermost layer consists of protective wear layer and decorative layer. Second layer is the wooden composite core, typically MDF or HDF (medium – or high density fiberboard). The third layer is a watertight layer (Krono, 2018, Pierce, 2016). This means that only the edges of laminate are bare wood based panels. Therefore the formaldehyde emitting surface is limited.

The single source contribution was around twice the limit of 10 µg/m³ chosen as an indicative threshold for minor sources. However, the formaldehyde emitting surface is small, and after constructing the floor the edges are enclosed within surrounding panels, it was decided to consider this as a minor source. In addition, wood based panels used for laminate production will be subjected to their own restriction.

Cooking

During cooking the formaldehyde emissions are expected from cooking process itself and burning fuel (gas).

The formaldehyde concentrations from cooking process itself were in the range 4 – 27 µg/m^3, measured in the oil fumes above the pan (Peng 2017).

The indoor formaldehyde concentration, from both cooking process and the burning fuel (if applicable) were as follow:

Table 17: Concentrations of formaldehyde during selected cooking tests (Salthammer 2017).

Activity	Oven	Condition	Kitchen [µg/m³]	Outdoor [µg/m³]
Oven cleaning	Gas	Standard	417.3	2.7
Broil fish	Gas	Standard	129.3	1.5
Oven cleaning	Electric	Standard	224.5	0.8
Broil fish	Electric	Standard	129.4	0.4
Pork roast	Gas	Aluminum pan, top burner	49.1	1.0
Pork roast	Gas	Exhaust vent., top burner	36.5	1.1

There is little difference in formaldehyde emissions between electric and gas stove.

Formaldehyde emissions were higher during the oven cleaning activity than during cooking. It should be noted, that European stoves are usually not equipped with an oven cleaning function.

Concluding, the provided data was sufficient to identify cooking as a one of the major temporary formaldehyde sources.

Ethanol fireplaces

In Schripp et al. (2014), eight measurements were performed, combining four different fireplaces with three types of ethanol fuel (all fuels were of technical quality and blended with ethanediol, 2-butanone (MEK) or isopropyl alcohol). There were significant differences in the release of formaldehyde. It could be only speculated about the reasons; one of them might be combustion process differences in various types of burners. It was shown by several authors that high emissions of organic oxygenates, which includes formaldehyde as one of the major products, might be expected from incomplete combustion of biofuel (Kohse-Höinghaus et al. 2010, Sarathy et al. 2014).

Table 18: Mean formaldehyde concentrations and calculated mean emission rates during the burning phase of ethanol fireplace with different types of fuel (Schripp et al. 2014).

Type of fuel	Formaldehyde mean room concentration [µg/m³]	Formaldehyde maximum room concentration [µg/m³]	Emission rate [µg/h]
O1 – ethanol (98%)	160.9	257.93	5380

O1 – ethanol (94%)	318.11	560.07	10637
O1 – ethanol (94%)	20.88	42.99	698

ppb to µg/m³ recalculated with http://www.aresok.org/npg/nioshdbs/calc.htm, using Mw = 30.03

For this combustion processes it was not possible to calculate emission rate distributions, emission rates are calculated from maximum concentrations. Consequently, only concentration ranges can be provided.

It is noted that emission of formaldehyde from ethanol fireplaces does not fall within the REACH regulation. Further information on such fireplaces and the effects on indoor air quality are described in a report by the European Commission titled "Study on alcohol-powered flueless fireplace combustion and its effects on indoor air quality" (2015). The report contains detailed analysis of this issue, together with conclusions and practical recommendations how to minimalize emissions of several volatile pollutants from ethanol and gel fireplaces (EC 2015). These recommendations are considered to be an advisable way to move forward.

Concluding, the provided data was sufficient to identify ethanol fireplaces as a one of the major temporary formaldehyde sources.

Wood combustion in fireplaces and wood stoves

Depending on the type of fireplace ovens or wood stoves, wood type and humidity, and the local room conditions, wood combustion may contribute to the indoor formaldehyde concentration in various degrees: from statistically insignificant to more than three times initial concentration.

Table 19. Formaldehyde concentrations in private homes before and during operation of wood burning fireplace ovens (Salthammer et al. 2014).

Oven	Before operation [µg/m³]	During operation [µg/m³]
1	14.74	22.11
2	17.2	22.11
3	19.65	67.55
4	19.65	41.76
5	12.28	19.65
6	23.34	24.56
7	12.28	23.34

ppb to µg/m³ recalculated with http://www.aresok.org/npg/nioshdbs/calc.htm, using Mw = 30.03

Air Cleaning devices and photocatalytic paints

The purpose of air cleaning devices and photocatalytic paints is to clean the indoor air from organic pollutant be degrading them to H_2O and CO_2. Unlikely, during the photocatalytic reaction also undesired by-products, especially formaldehyde, are formed.

Table 20: Initial and final steady-state formaldehyde concentrations in a 20 m³ chamber under different conditions during operation of PCO filters (Salthammer 2017)

UV-type/experiment	UVC/2	UVC/3	UVC/4	UVA/5	UVA/6
$C_{initial}$ [µg/m³]	30 +/- 1	20 +/- 1	29 +/- 5	27 +/- 4	29 +/- 1
$C_{steady\text{-}state}$ [µg/m³]	44 +/- 1	33 +/- 1	22 +/- 3	18 +/- 1	11 +/- 1

Table 21: Steady-state formaldehyde concentrations in a 14.75 m³ stainless-steel chamber in absence and presence of air freshener and operation of an air cleaning device (Salthammer 2017).

Formaldehyde steady-state concentration [µg/m³]			
Background	Air cleaner	Air cleaner + air freshener	Air freshener
17.6 +/- 2.8	19.3 +/- 2.8	49.3 +/- 3.9	45.9 +/- 2.7

General conclusion on consumer exposure from formaldehyde indoor, available information and possible further actions

The registrant's report on formaldehyde emission sources was considered to be well-written and provides a complete overview of the available open-source/public and registrant's own information, presented in a clear way and including summarizing tables. Data analysis was provided in transparent way and conclusions were properly justified. There is sufficient data for the further follow-up actions.

Based on the provided information, the eMSCA concluded that the wood based panels are the main continuous formaldehyde indoor source. Therefore restriction on emission from wood based panels – setting an emission limit to reduce emissions – is proposed as an appropriate Risk Management Measure. The Restriction process has been already started by ECHA.

Combustion sources (fireplaces, cooking, candles, incense) were identified by the eMSCA as the main temporary sources.

7.12.2. Environment

Not evaluated.

7.13. Risk characterisation

7.13.1. Risk characterisation for workers

Analysis of Registrant's data

Registrants' assessment for occupational inhalation risks is based on :

- 2013 CSR: monitoring data gathered from downstream users, a literature analysis, supplemented by model estimates for situations with insufficient useful user and literature data with ECETOC TRA version 3.0 in a first tier and refined with ART

when necessary[10]. Considering the proposed DNELs, some occupational sectors are at risk as showed in the table below;

- 2015 CSR update: only modelling data using EasyTRA 4.0.0. The registrants considered that the previous data gathered in the 2013 CSR support the model estimations in the CSR. Risk characterisation was undergone with DNELs of 0.6 ppm for short term exposure and 0.3 ppm for long term exposure. All RCRs are below 1.

Nevertheless, risk characterisation based exclusively on modelling data is not sufficient enough, considering all the uncertainties related to model estimations and choices of modelling parameters. In particular, corrective factors were applied for protective equipment reducing final exposure estimations. All relevant datasets on formaldehyde exposure should be taken into account for risk characterisation, including modelling and monitoring data, especially for long-term exposure as formaldehyde is a carcinogenic compound. For these reasons, 2015 CSR exposure data are considered insufficient for workers risk characterisation.

Table 22. Sectors at risk depending on monitored or modelled formaldehyde concentrations for short and long term exposures, from 2013 Registrant CSR

Long-term exposure	**DNEL 0.3 ppm (0.37 mg/m^3)**
Monitoring data from downstream users (90th Percentile, personal)	Manufacturing of formaldehyde and Resins (during transfer of formaldehyde and Resins) Resin / chemicals manufacturing (during control of the Resin / chemicals manufacturing process) Panel production (during paper impregnation of wood based panels and maintenance in the wood panel industry)
Modelling data (75th Percentile)	Production of fertilizer granules (PROC 8b) Industrial production of foams, bonded particulate, bonded fibers/mats, paper and impregnation of leather and textile (PROC 3,4,7,8a,8b,9,10,13) Professional production of foams and use of resins in wood applications (PROC 10,23,25)
Short-term exposure	**DNEL 0.6 ppm (0.74 mg/m^3)**
Monitoring data from downstream users (90th Percentile, personal)	Panel production (during paper impregnation of wood based panels and maintenance in the wood panel industry)
Modelling data (75th Percentile)	Industrial production of foams, bonded particulate, bonded fibers/mats, paper and impregnation of leather and textile (PROC 1,2,5,6,14) Professional production of foams and use of resins in wood applications (PROC 10)

[10] ECETOC TRA 3.0, personal long-term, 75th Percentile. Except for Formalin (60% formaldehyde): ART 1.0, 75th Percentile.

Additional data: extraction from the French COLCHIC database

COLCHIC is a French database collecting occupational exposure measurements carried out by the chemical laboratory services of CARSAT (Health insurance) and the INRS institute (Mater, 2016). These measures are not undertaken for regulatory control but for the purpose of prevention. They are implemented by safety engineers and controllers but can also be requested by occupational physicians or companies directorates. These measurements cannot be generalised to all situations found in the workplace and are not representative of one specific occupational sector. They can however give an overview of ocupationnal exposure in SMEs (which is not probably the case of data provided by Industry in the framework of Substance Evaluation).

In particular, measurements gathered in the COLCHIC database are undertaken without any respiratory protective equipment. No exposure reducing factor is applied (whether nominal nore assigned). Measurements are not adjusted on the time of occupational exposure but correspond to the concentrations measured during the sampling time. A statistical exploitation is proposed depending on the number (n) of measures for one occupational sector/task: probabilistic approach if n>20, mean and standard deviation if 10<n<19, no data if n<9.

The use of the database and the statistical analysis for formaldehyde exposures were done by INRS in two periods of time : 2000-2006 and 2007-2013 estimating the impact of a French decree of 13th of July, 2006 adding processes emitting formaldehyde to the list of substances, preparations and carcinogenic processes from the 1st of January, 2007. An analysis by sectors, activities and tasks was provided, showing numerous specific sectors at risk, not cited in the registration dossier. The following table gives an overview of sectors for which COLCHIC collected formaldehyde concentrations (90th percentile) above DNELs.

Table 23. Occupationnal sectors at potential risk (exposure data from French COLCHIC database for the period 2007-2013)

Long-term exposure	**DNEL 0.3 ppm (0.37 mg/m^3)**
Activity sector at risk (as cited in COLCHIC)	Building industry and civil engineering Chemicals, rubber and plastic industries Wood, paper, furniture, textile, clothes, leather and hide and earthenware Public health services Private health services
Short-term exposure	**DNEL 0.6 ppm (0.74 mg/m^3)**
Activity sector at risk (as cited in COLCHIC)	Public health services Private health services

1) Building industry and civil engineering

The global exposure value has decreased from 1.54 mg/m^3 for the 2000-2006 period to 0.48 mg/m^3 for the 2007-2013 period.

For specific tasks, exposure values remain so high for the 2007-2013 period that additional RMM would be necessary:

- Roofing with all materials (except plumbing). 90th percentile exposure value = 0.75 mg/m^3
- Joinery (manufacture and installation) including or not the structural wood: 90th percentile exposure value = 0.42 mg/m^3

2) Chemicals, rubber and plastic industries

The global exposure value has decreased from 0.27 for the 2000-2006 period to 0.15 mg/m^3 for the 2007-2013 period.

Exposure values remain high for specific tasks for the 2007-2013 period:

- Production of base-products for pharmacy, alkaloids, glycosides and derivatives, algae extracts: 90th percentile exposure value = 0.55 mg/m^3
- Casting machine operations and controls: 90th percentile exposure value = 0.66 mg/m^3

3) Wood, paper, furniture, textile, clothes, leather and hide and earthenware

The global exposure value has decreased from 0.48 for the 2000-2006 period to 0.40 mg/m^3 for the 2007-2013 period.

Exposure values remain high for specific tasks for the 2007-2013 period:

- Wood based panel production (chopped, ground, defibrillated wood): 90th percentile exposure value = 0.42 mg/m^3
- Production of wooden frame pieces, grinding and shaping including brush woods: 90th percentile exposure value = 0.73 mg/m^3
- Machining, assembling, welding, bonding, assembly lines: 90th percentile exposure value = 0.47 mg/m^3
- Serial production of building carpentry: 90th percentile exposure value = 0.47 mg/m^3
- Impregnated, tar, coated and painted paper production: 90th percentile exposure value = 0.69 mg/m^3

4) Public health services

Based on the COLCHIC data registered during 2000-2006 or 2007-2013, the global exposure value has decreased from 0.67 to 0.33 mg/m^3.

Concerning specific tasks, some have such a value that additional RMM would be necessary:

- 751AE (2007-2013) in hospital authority: Anatomopathological examinations (lamella preparation, tissue binding…): 90th percentile exposure value = 0.47 mg/m^3

5) Private health services

Based on the COLCHIC data registered during 2000-2006 or 2007-2013, the global exposure value has decreased from 1.19 to 0.65 mg/m^3, which is still far above the DNEL of 0.3 ppm derived for long-term exposure.

Concerning specific tasks, some have such a value that additional RMM would be necessary and useful:

- Medical analysis outside hospital services: 90th percentile exposure value = 0.92 mg/m^3
- Biological laboratories: 90th percentile exposure value = 1.07 mg/m^3
- Anatomo-pathology: 90th percentile exposure value = 0.64 mg/m^3

In October 2015, the French Ministry of Labour published a French occupational exposure survey, focusing on formaldehyde: 153,600 workers were registered in 2003 *vs* 122,500 in 2010 (i.e. a decrease of 20%). Exposure measures implemented on sites showed that formaldehyde exposures were mainly short term and of weak intensity. An increase of 32% of the use of collective protective equipment has been observed in the wood industry (general ventilation) whereas health services sectors have implemented personal protective equipment.

Additional data on thanatopraxy sector

In 2009, ANSES demonstrated high levels of short-term formaldehyde exposure in thanatopraxy, based on published literature as this professional sector is not considered by the French COLCHIC database. Published studies showed mean short-term formaldehyde levels from 0.11 to 17 ppm, measured during the preparation of formaldehyde solution before embalming. Compared to the ANSES short-term DNEL of 0.6 ppm, this sector seems clearly a professional sector at risk.

Summary of the risk characterisation

Considering these short-term and long-term DNELs, the Risk Characterisation Ratios (RCRs) have been calculated based on exposure data from the 2014 SEv Report (2013 registrant CSR) and from the French COLCHIC database.
The table below provides the list of the uses at risk (RCRs > 1).

Table 24. Occupationnal sectors at potential risk (exposure data from 2013 registrant CSR and French COLCHIC database)

Identified uses of formaldehyde from Registrant
Manufacturing of formaldehyde and resins
Resin / chemicals manufacturing
Panel production (wood panels – paper impregnation, lamination, maintenance and cleaning)
Fertiliser granules production
Industrial production of foams, bonded particulates, bonded fibers/mats and paper
Impregnation of leather and textile
Professional use: production of foams
Professional use: resins in wood applications
Identified uses of formaldehyde from COLCHIC
Building industry and civil engineering
Chemicals, rubber and plastic industries
Wood, paper, furniture, textile, clothes, leather, hides and earthenware
Public health services Private health services

7.13.2. Risk characterisation for consumer

Please, see 7.12.1.2.

The initial concern was the (aggregated) consumer exposure to formaldehyde from several sources in indoor air. The registrant submitted two additional reports (Marquart 2013 and Salthammer 2017) on formaldehyde indoor concentrations and formaldehyde emission sources.

The latest Registrant's report submitted as a response to ECHA's Decision gave much more details than the first additional report (2013) and allows distinguishing the main formaldehyde indoor sources, both temporary and continuous.

Similarly to the indication in the Decison, taking into account the new information, there is still concern for the consumer exposed to formaldehyde via indoor air. When DNEL from Registrants of 100 µg/m3 is compared to the aggregated exposure from the reference room, there is still a risk. The main contributors are the wood based panels (without

covering or taking into account sink and aging) from continuous sources and combustion sources from temporary sources.

7.14. References

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7.15. Abbreviations

AF	Assessment Factor
ANSES	French Agency for Food, Environmental and Occupational Health Safety
BOEL	Binding Occupational Exposure Limit
CAD	Chemical Agents Directive
CARSAT	French Health Insurance
CLH	Classification and labelling harmonisation
CLP	Classification, Labelling and Packaging of substances and mixtures
CMD	Carcinogens and Mutagens Directive
CMR	Carcinogenic, mutagenic, reprotoxic
CoRAP	Community rolling action plan
CSR	chemical safety report
DN(M)EL	Derived No(Minimal) effect level
ECHA	European Chemicals Agency
eMSCA	evaluation Member State Competent Authority
EPF	European Panel Federation
ERC	Environmental Release Category
ES	Emission Scenario
eSDS	extended Safety Data Sheets
EU	European Union
FAD	formaldehyde dehydrogenase
FR	France
GI	Gastro-intestinal
GPMT	guinea pig maximisation test
HDF	high density fibreboard
INRS	French institute for occupational safety and health
LEV	local exhaust ventilation
LLNA	local lymph node assay
LOAEC	Lowest observed adverse effect concentration
MDF	medium density fibreboard

MF	Melamine-Formaldehyde
NCI	National Cancer Institute
NL	the Netherlands
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NPC	nasopharyngeal cancer
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OSB	oriented strand board
PB	particleboard
PF	Phenol-Formaldehyde
PLY	Plywood
PROC	Process Category
RAC	Risk Assessment Committee
RCR	risk characterization ratio
RCR	Risk Coefficient Ratio
REG	registrant
RIVM	National Institute for Public Health and the Environment
RMM	risk management measure
RMO	Risk Management Option
RMOA	Risk Management Option Analysis
RPE	Respiratory Protective Equipment
RPE PF	Respiratory Protective Equipment Protection Factor
RRS	Risk Reduction Strategy
SCOEL	Scientific Committee on Occupational Exposure Limits
SME	Small and Medium Enterprises
SU	Sector End Use
SVHC	substances of very high concern
UF	Urea-Formaldehyde
UVCB	Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials
WHO	World Health Organization