

Helsinki, 06 October 2015

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For formaldehyde, CAS No 50-00-0 (EC No 200-001-8)

Addressees: Registrant(s)¹ of formaldehyde (Registrant(s))

This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent for comments, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrant(s) holding active registrations on the day the draft decision was sent for comments are *not* addressees of this decision if they are: i) Registrant(s) who had on that day registered the above substance exclusively as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrant(s) who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on a joint evaluation by the French Agency for Food, Environmental and Occupational Health Safety (ANSES) on behalf of the French Competent Authority² and by the National Institute for Public Health and the Environment (RIVM) on behalf of the Dutch Competent Authority (evaluating MSCAs), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 29 April 2014, i.e. the day on which the draft decision was notified to the Registrant(s) pursuant to Article 50(1) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authorities of France and the Netherlands have initiated a substance evaluation for formaldehyde, CAS No 50-00-0 (EC No 200-001-8) based on registration(s) submitted by the Registrant(s) and other

¹ The term Registrant(s) is used throughout the decision, irrespective of the number of Registrant(s) addressed by the decision.

² FR leads the Evaluation and is the responsible competent authority in the meaning of Article 45(2) of REACH.

relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health/CMR, exposure/wide dispersive use, worker exposure and aggregated tonnage, formaldehyde was included in the Community rolling action plan (CoRAP) for substance evaluation and to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authorities of France and the Netherlands were appointed to carry out the joint evaluation. The evaluating MSCAs did not evaluate the environmental related endpoints of the registered substance.

The evaluating MSCAs considered that further information was required to clarify the abovementioned concerns. Therefore, they prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. They submitted the draft decision to ECHA on 19 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant commenting phase

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCAs without delay.

The evaluating MSCAs considered the comments received from the Registrant(s). On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 16 January 2015 the evaluating MSCAs notified the Competent Authorities of the other Member States and ECHA of the draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 20 February 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCAs reviewed the proposals for amendment received and amended the draft decision.

Referral to Member State Committee

On 2 March 2015 ECHA referred the draft decision to the Member State Committee.

By 23 March 2015 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments on the proposal(s) for amendment of the Registrant into account.

After discussion in the Member State Committee meeting on 20 to 23 April, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 23 April 2015. ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision using the indicated instructions and, where relevant, an update of the Chemical Safety Report:

1. Consideration of hazards and risks related to the presence of methanol above 10% w/w as an additive in some aqueous solutions of formaldehyde.
- 2.a) A review of literature data including the Registrant(s)' own data on the emission rates (in $\mu\text{g}/\text{m}^2/\text{h}$), comprising time-dependency (where available) for the major sources and their relative contribution to the total indoor air concentration of formaldehyde. This investigation should provide a ranking of indoor sources of formaldehyde, using emission rates and the decrease of emission rates over time as a basis to rank the sources. The sources considered by the Registrant(s) shall in any case include – but need not be limited – to the following:
 - building/construction materials such as wood based plate materials for ceiling and flooring and mineral wool;
 - furniture and other UF pressed wood products like hardwood plywood paneling and fiberboard;
 - paints;
 - wallpapers;
 - textiles such as curtains, carpets;
 - cleaning agents; and
 - combustion sources such as cooking.

The emission rates should be reported in such a way that it allows for a comparison of the various sources. Based on this comparison, a justified ranking of the indoor formaldehyde sources shall be provided, using emission rates and the decrease of emission over time.

- 2.b) A revision of all the relevant consumer exposure scenarios (for specifications see Section III) , taking into account combined exposure to the relevant sources, as well as the information generated following the request 2.a.

The exposure scenarios shall be based on reasonable worst-case emission rates and representative emission parameters, such as surface of emitting material per European Reference room and exposure parameters. Distinct scenarios shall be conducted, with and without occasional sources (e.g. cleaning agents and cooking) .

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **13 October 2017** an update of the registration dossiers containing the information required by this decision and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

1. Consideration of hazards and risks related to the presence of methanol above 10% w/w as an additive in some aqueous solutions of formaldehyde

Formaldehyde is produced in the form of aqueous solutions and all solutions in the registration dossiers contain methanol either as an impurity or as an additive used to stabilise the solution and limit polymerisation of formaldehyde that would modify the properties of the substance.

The definition of a substance under REACH (article 3(1)) states that it includes "any additive necessary to preserve its stability and any impurity deriving from the process used". The registration of the substance shall therefore consider the hazards and risks related to the substance including its additives or impurities.

Methanol has an harmonised classification for its physical and health hazards.

In particular, some formaldehyde solutions that are registered contain more than 10% w/w of methanol. Above 10% of methanol, these solutions are classified as Flammable Liquid, Cat. 3 according to Annex VI of EC 1272/2008 and this hazard should be assessed, as required in REACH Art 14(4)(a). In addition, REACH Annex I requires in Chapters 2, 5 and 6 an assessment of the hazards of physicochemical properties of the reported substance and therefore the resulting risk.

In none of the exposure scenarios, the risks originating from the flammability and other physicochemical hazards are specifically addressed. This means that based on the available information, the risks of flammability related to the handling of formaldehyde solutions containing more than 10% of methanol cannot be properly evaluated.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) of formaldehyde solutions containing more than 10% w/w of methanol are required to address and discuss the hazards and risks related to the presence of methanol above 10% w/w in formaldehyde solutions. The information shall be submitted by the Registrant(s) of formaldehyde solutions containing more than 10% w/w of methanol in a revised version of their specific Chemical Safety Report.

Consumer exposure indoors

- 2.a** A review of literature data including the Registrant(s)' own data on the emission rates (in $\mu\text{g}/\text{m}^2/\text{h}$), comprising time-dependency (where available) for the most important sources and their relative contribution to the total indoor air concentration of formaldehyde.
- 2.b** A revision of all the relevant consumer exposure scenarios.

Link to the concern

The initial concerns on human health, wide dispersive use and consumer exposure relates to the uncertainty in the actual consumer exposure due to formaldehyde concentrations in indoor air. More specifically the data provided by the Registrant(s) does not allow drawing conclusions on the identification of the major sources and what is the relative contribution of each source type.

Formaldehyde has been recently classified as Carcinogen 1B and Mutagen 2 (will be placed

on Annex VI of Regulation EC 1272/2008). Substances so classified are normally included in entry 28 of Annex XVII, which restricts the use of such substances on their own or in mixtures for consumer use. However, this is not an automatic process but needs a decision by the Commission in accordance with Article 68(2). The use of such substances in articles can also be covered under Article 68(2) but no such decisions have yet been proposed. There are, however, many products with a relatively high potential for releasing formaldehyde into indoor air such as pressed wood products, insulation foams and textile.

It should be noted that (most) indoor sources of formaldehyde do not contain formaldehyde as such, but can emit this substance as a product of hydrolysis of, for example, urea-formaldehyde resins used to produce many articles used indoor (e.g. furniture and textile), further referred to as "secondary emissions". These emissions may be significant for days or for months, depending on the source type.

There are also cleaning agents (both containing and not containing formaldehyde itself, but formaldehyde releasers), paints and combustion sources which may contribute to the indoor concentration on occasional basis.

Information provided by the Registrant(s) in the additional report (report uploaded as an Annex to the CSR of the lead registrant dating July 2013, to be further referred to as "additional report") shows that there are situations in which indoor air formaldehyde concentrations are higher than the DNEL of 0.1 mg/m³ as proposed by the Registrant(s)³. Although ECHA recognises that this DNEL is based on sensory irritation, irritation is claimed to be one of the underlying mechanisms of carcinogenicity (RAC opinion on classification of formaldehyde, adopted 28 November 2012). As mentioned before, formaldehyde has been recently classified as Carc. 1B and Mutagen 2. Therefore, in some situations a risk for consumers cannot be excluded and thus needs to be addressed.

Moreover, uncertainty exists on the sources contributing to the indoor air formaldehyde concentration and their relevant significance. Overall, the available information on indoor air concentration and contributing sources in the registration dossier(s) (including the additional report) is not considered sufficient to demonstrate safe use and does currently not allow the identification of appropriate risk management measures in order to ensure safe use.

What relevant information is available?

The available information from the registration dossier(s) and the additional Registrant(s)' report suggests 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 proposed by the Registrant(s)). Because of this concern, it is necessary to gather sufficient data that allow the performance of a risk assessment, for which the contribution from different sources is needed.

In the Chemical Safety Report (CSR) there is no assessment of the exposure of consumers. Relying on article 14(2) of REACH the Registrant(s) claim that a chemical safety assessment (CSA) for the exposure of consumers to formaldehyde is not required because the substance is present in mixtures in concentrations below 0.1%. According to the Registrant(s) the rationale of article 14(2) can be applied to articles like panel boards and wallpapers that may contain formaldehyde in equally low amounts ("percentages of formaldehyde in the final article are below 0.1%").

³ Note that for the purpose of this evaluation, the comparison between measured or calculated concentrations indoor and the Registrant(s) DNEL is powerful enough to justify the concern.

The additional report provided by the Registrant(s) confirms the likelihood of concentrations of formaldehyde in indoor air above the DNEL proposed in the registration dossier, especially in newly built and refurbished houses. For example, according to a recent study (2014) described in the additional Registrant's report, where measurements were performed in 123 new buildings, six from 485 measurements were above the DNEL (even if the final study report has not been submitted to the evaluating MSCAs, it was found to be conclusive enough to take the data into account). In addition, in other studies (performed in years 1999 – 2011) and reviewed in the additional report, indoor formaldehyde concentrations exceed the DNEL proposed by the Registrants in 5% (on average) of all measurements in old and new buildings.

The Registrant(s) conclude that as the DNEL was exceeded in just over 1% and 5 % of the measurements, there is no risk for consumers. Measured concentrations are not personal exposures, particularly related to long-term effects. Personal exposure is a measured average concentration of the person over a period of time and people, mostly, move between locations. Because of this, the "exposure" for the majority of the people will likely be below the theoretical possible maximum as they go about their normal lives and are exposed to varying levels during work, rest and play. However, ECHA notes that consumers include also the most vulnerable groups, such as infants, elderly people or people with poor health conditions, for which exposure levels are likely to be higher than for the average consumer described above. These groups represent a non negligible part of the European population. ECHA is of the opinion that the risk associated with exposure to the above mentioned concentrations of formaldehyde could still pose a risk to, but may not be limited to, these groups of consumers and thus it needs to be further investigated. The DNEL is based on effects that have been linked to carcinogenicity and as such it is of utmost importance that this level is not exceeded.

The above information is in response to the proposal for amendment in relation to further clarifications on the concern for consumers in terms of risks and effects. Furthermore, it also responds to the Registrant(s)' comments that there is no need for generating additional information because the available data do show that real exposure levels are, except in exceptional cases, below the DNEL.

The additional report provided by the Registrant(s) gives information on emission rates from some, but not all, formaldehyde releasing products, focusing on wood-based products, paint and furniture. Moreover, it is not clear from this report whether the provided emission rates are the most representative for the different product categories. This report indicates that formaldehyde emission from articles changes in time (both increase and decrease), but without enough details to draw a clear time-emission dependency.

The existing literature data pointing at elevated indoor exposure are further supported by the outcome of an exposure scenario modeling, included in the additional report provided by the Registrant(s). For this exposure scenario the combined exposure of three sources is estimated in a European Reference Room, using current industry emission standards for different types of wood based panels of 0.124 mg/m²/h. The three sources included were wood-based construction ceiling and flooring and a piece of furniture (large wardrobe). The estimation resulted in an indoor air concentration of formaldehyde just below the DNEL, accounting to 0.093 mg/m³. However, the pressed-wood sources included in the calculations are assumed to have relatively low emission rates. As outlined in the additional report, calculations with higher emission rates (i.e. E2 quality pannels) would result in concentrations above the DNEL. ECHA would like to note that the inclusion of other possible sources (textile, combustion etc.) is expected to lead to even higher indoor air concentrations. Furthermore, ECHA is of the opinion that actual, measured emission rates

should be preferably used when conducting the exposure scenario instead of emission standards.

In conclusion, the available data indicate that there is a potential risk for consumers. Data on formaldehyde emissions from main sources in indoor air is needed to further substantiate the levels as well as the contribution from the various sources. The available information is not sufficient to make a comparison of formaldehyde sources in order to conclude which are the most important for the purposes of risk assessment relating to consumers and for which risk management options could be proposed.

It is in the interest of the Registrant(s) to gather information on the relative contribution of sources from his own supply chain, to be compared with estimates of relevant combined consumer exposure.

Justification why new information is needed

According to the REACH legislation, article 14(2) is applicable only to mixtures, and not to articles. The Chemical Safety Report contains information on formaldehyde used in production and formulation of a number of different articles and mixtures that are expected to enter the consumer market (like furniture, cleaning agents, textiles etc.). Some of the articles containing urea-formaldehyde resins are sources of formaldehyde in the indoor environment (like wood-based construction panels and flooring). The CSR does not take into account these secondary emissions. The additional report gives a literature overview of measured indoor formaldehyde concentrations and the incomplete overview of the secondary emission sources. The additional report describes also, but only briefly, the combined exposure to these different sources.

Therefore, the available information (both in the CSR and in the additional report) does not allow to conclude on the safe use of the formaldehyde containing/emitting products in the indoor environment and on the conditions under which there may still pose a risk.

More specifically, it is not clear what is the absolute and relative contribution of the different sources and how the contribution of the different sources evolves in time. The Registrant(s) (additional report) assume that wood-based construction material and furniture are the major sources of formaldehyde emission in indoor air, but data to support this conclusion is not sufficient. Summarising, the available information is enough to raise the concern for indoor formaldehyde concentration, but is insufficient to conclude on which source(s) contribute the most to this indoor air concentration.

Therefore, it is necessary to gather information on the contribution on the different sources, including their emission rates and type dependency. An emission rate can be defined as a product specific factor typically describing the mass of a chemical emitted from a product, and is expressed per exposed area of the product per unit time ($\mu\text{g}/\text{m}^2/\text{h}$) or per weight per unit time ($\mu\text{g}/\text{g}/\text{h}$). Emission rates differ for several articles, in the extent/quantity of free formaldehyde emitted, and differ over time. Information on the absolute emission rates and relative contribution (with surface or volume of an article present indoor, together with frequency of use; furniture will emit formaldehyde continuously, but cleaning agents only occasionally) from different sources is needed to perform a risk assessment to select major sources of indoor formaldehyde emission.

What is the request

The required information is aimed at the following different objectives:

- Identify the relative contribution of formaldehyde indoor emitting products or sources and a revision of all the relevant consumer exposure scenarios;
- Priority setting of sources which may need to be regulated in terms of formaldehyde emission.

The proposal for amendments addressed several aspects, amongst which the proportionality and the scale of the request. The Registrant(s)' comments expressed the same concern. Following the discussion that took place at the Member States Committee, ECHA agrees that currently no new measurements are required. The request in the draft decision was amended and is now focussed only on available literature data, as well as the Registrant(s)' own data. The Registrant(s) have already partly provided this data in the additional report; however, not all relevant sources were taken into account and no comparison of emission sources/rates was provided. Examples of overview papers of indoors formaldehyde sources, which may be used to supplement the already available information are given in the reference list. The Registrant(s) are encouraged to expand this list.

The Registrant(s) should propose and motivate, which are the main indoor formaldehyde sources.

The Registrant(s) should provide a detailed list of the different types of major formaldehyde sources. To the extent it is required for the purpose of the risk assessment and identification of major sources, the list should distinguish types of sources by the types of materials. For example, for textile, the fabric type (cotton, linen, synthetic fabrics) and the type of formaldehyde emitting coating is defining the material type. For wood products this is a combination of wood product type (for example softboard) and resin adhesive type (polymeric resin of formaldehyde with urea, melamine etc.).

ECHA has no data on which adhesives/coating are used in certain material types. As composition of adhesive/coating is essential for emission rate, it is important to establish this link to allow the proper grouping of materials in risk assessment and undergo any subsequent potential risk management measures. If only one type of adhesive or coating is used in a certain type of material, this information should also be provided.

The temporal dependency of emission rates is needed to distinguish sources contributing significantly on acute and chronic basis to indoor formaldehyde concentration. Information on changes in emission rates over time should be provided, where available.

In relation to the revision of the consumer exposure scenarios further specifications are provided following proposal for amendments and Registrant(s) comments.

The exposure scenarios shall be based on reasonable worst-case emission rates and representative emission parameters, such as the surface of emitting material in a European Reference room and relevant exposure parameters. Distinct scenarios shall be conducted, with and without occasional sources contributing. The Registrant(s) should develop a realistic worst case scenario, intended as the one with maximum loading rates (i.e. the surface of emitting material per volume in the room) and at the peak of the emission rate. If the calculated formaldehyde concentration is below the DNEL as provided by the Registrant(s), no further information is needed. If the calculated formaldehyde concentration is above the DNEL, additional scenario's should be provided, taking into account the variability in the presence or absence of each major source. For example:

- presence or absence of ceiling panels,

- presence of floor panels versus carpeting,
- textile-covered furniture versus wood (products) furniture,
- shutters versus curtains.

This analysis will show the influence of different sources on the indoor formaldehyde concentration and will form the basis for possible further risk management measures.

The Registrant(s) have expressed their doubts about the relevance and legal grounds of the request for information on emission rates from articles as a result of urea-formaldehyde resin hydrolysis.

The duties and responsibilities of the Registrant(s) are not considered to be limited only to the manufacturing process, but actually to the entire life-cycle of the monomer. If the polymer contains some residues of the monomer and this could be released during the course of its uses, e.g. when the polymer is degraded, then the registrant is still responsible to address the risks associated with the exposure to the monomer released by the polymer. Therefore the Registrant(s) are considered to be responsible for the secondary formaldehyde emissions from polymeric resins.

The Registrant(s) have also expressed their doubts about the relevance and legal grounds of the request for emission data from sources which are outside of their supply chain. ECHA would like to stress, that this data is necessary to investigate the proportional contribution from all sources, in order to model representative scenarios, assess the risk and address the most important sources, if necessary. If some of the sources are left out, the relative contribution of the remaining sources, including those in the supply chain of the Registrant(s), will increase.

In addition, such a semi-complete picture of the Registrant(s)' supply chain emissions may lead to incorrect and insufficient further risk management measures. If, for example, textile and textile-covered furniture are in fact the main contributor to the indoor formaldehyde concentration, and emission data from textile (articles) will not be provided, other sources may be subjected to further actions (for example wood products).

Conclusions

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information in the form of an updated Chemical Safety Report (CSR) using the specified approaches where applicable:

2.a) A review of literature data including the Registrant(s)' own data on the emission rates (in $\mu\text{g}/\text{m}^2/\text{h}$), including time-dependency (where available) for the major sources and their relative contribution to the total indoor air concentration of formaldehyde. This investigation should provide a ranking of indoor sources of formaldehyde, using emission rates and the decrease of emission rates over time as a basis to rank the sources. The sources considered by the Registrant(s) shall in any case include – but need not be limited – to the following:

- building/construction materials such as wood based plate materials for ceiling and flooring and mineral wool;
- furniture and other UF pressed wood products like hardwood plywood paneling and fiberboard;
- paints;
- wallpapers;

- textiles such as curtains, carpets;
- cleaning agents; and
- combustion sources such as cooking.

The emission rates should be reported in such a way that it allows for a comparison of the various sources. Based on this comparison, a justified ranking of the indoor formaldehyde sources shall be provided, using emission rates and the decrease of emission over time.

2.b) A revision of all the relevant consumer exposure scenarios taking into account combined exposure to the relevant sources, as well as the information generated following the request 2a.

The exposure scenarios shall be based on reasonable worst-case emission rates and representative emission parameters, such as surface of emitting material per European Reference room and exposure parameters. Distinct scenarios shall be conducted, with and without occasional sources (e.g. cleaning agents and cooking) .

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at <http://www.echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised^[4] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

^[4] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

References:

(BfR 2005) Inhalative Exposition des Verbrauchers gegenüber Formaldehyd, Aktualisiertes Diskussionspapier* des BfR vom 30. April 2005, http://www.bfr.bund.de/cm/343/inhalative_exposition_des_verbrauchers_gegenueber_formaldehyd.pdf

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(EPA 2001) CANDLES AND INCENSE AS POTENTIAL SOURCES OF INDOOR AIR POLLUTION: MARKET ANALYSIS AND LITERATURE REVIEW, Environmental Protection Agency, January 2001, EPA-600/R-01-001, <http://nepis.epa.gov/Adobe/PDF/P1009BZL.pdf>