INVESTIGATION REPORT

FORMALDEHYDE AND FORMALDEHYDE RELEASERS

SUBSTANCE NAME: Formaldehyde
IUPAC NAME: Methanal
EC NUMBER: 200-001-8
CAS NUMBER: 50-00-0

SUBSTANCE NAME(S): -
IUPAC NAME(S): -
EC NUMBER(S): -
CAS NUMBER(S):-

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1. Summary

Formaldehyde has been under substance evaluation by France and the Netherlands. France identified risks for certain worker exposure scenarios and prepared a Risk Management Option Analysis for those uses. Based on the Netherlands' evaluation, ECHA requested further information from the registrants concerning the consumer exposure. ECHA has liaised with these Member States when preparing this report.

ECHA has identified several formaldehyde releasers that are not included in the lists of biocides or preservatives under the Biocidal Product Regulation (BPR) or the Cosmetic Product Regulation (CPR). Thus they are within the scope of REACH; the report provides information on the uses of these substances. Scientific literature and information received through the call for evidence was used in the identification. In addition, some substances which are biocides or preservatives under the concerned regulations are used in other applications, and also described in this report.

According to the stakeholders, it is important to provide a definition for formaldehyde releasers. As formaldehyde may be released from substances and mixtures intentionally or unintentionally and release may occur also from articles, ECHA has categorised formaldehyde releasers in the following groups:

1) formaldehyde releasers with the intentional release of formaldehyde falling under BPR and/or CPR,
2) formaldehyde releasers in the scientific literature or identified as such by the substances identified stakeholders, and

In addition to the above, ECHA has considered a third group of substances that are not defined as formaldehyde releasers but may potentially release formaldehyde as this substance is included in their composition. They are:

3) substances registered under REACH containing formaldehyde in their composition either as constituent of the substance or as impurity (potential formaldehyde releasers).

Uses of substances in group 3, are reported as described in the registration dossiers.

Exposure to formaldehyde released from new construction materials and when new furniture are used may be higher than in the average living conditions. There seem to be divergent views what can be regarded as protective limit value of formaldehyde in indoor air.

Based on the available information there appears to be a risk to workers from one or more uses of formaldehyde. In relation to consumer, there are many more uncertainties related to the exposure and the health based limit value to be used. In addition, there are uses of formaldehyde releasers that are likely to contribute to worker and consumer exposure and a number of such releasers (and potential releasers) have been identified as being within the scope of REACH. This issue needs further examination.

2. Report

2.1. Background

On 3 December 2015, ECHA received a request by the European Commission (Ares-ddg1.d1(2015)5962998)[1] to carry out preliminary investigation on formaldehyde (CAS no. 50-00-0) and formaldehyde releasers to assist the Commission in their consideration whether or not to request ECHA to prepare an Annex XV restriction dossier. The requested tasks were:

(1) to co-operate with France in their preparation of the risk management option analysis (RMOA) for formaldehyde and with the Netherlands in the Substance Evaluation (SEv) investigations on consumer exposure, and

(2) to investigate those formaldehyde releasers which are listed in the Annex V of the Cosmetic Product Regulation (EC) No 1223/2009 and then to investigate other known formaldehyde releasers, and their uses, other than for biocidal purposes.

Before detailing the work carried out by ECHA, it is useful to review the current regulatory status of formaldehyde and formaldehyde releasers.

- The classification of formaldehyde was amended by the Regulation (EU) No 605/2014 of 5 June 2014 to: Carc. 1B, Muta. 2, Acute Tox. 3 (oral), Acute Tox. 3 (dermal), Acute Tox. 3 (inhalation), Skin Corr. 1B and Skin Sens. 1.

- The Committee for Risk Assessment (RAC) has adopted opinions on harmonised classification concerning three formaldehyde releasers, i.e. 4,4'-methylenedimorpholine; [MBM], Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); [MBO] and Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1); [HPT]. RAC states that where data on [substance] are lacking data on the hydrolysis products formaldehyde [and other hydrolysis products depending of the substance] were used. The classification according to the opinions of RAC for all three substances is Carc. 1B and Skin Sens 1, including other substance specific hazard classifications (e.g. Aquatic Chronic 2 (except for MBM)).

- Formaldehyde is included in the Community Rolling Action Plan (CoRAP). The substance evaluation was a joint undertaking by France (leading the evaluation) and the Netherlands; France was responsible for addressing concerns to workers and the Netherlands responsible for addressing concerns for consumers and general population.

  Substance evaluation concerning workers was finalised in 2014, and concluded that there is a risk for workers for some activity sectors. Based on this conclusion, the French Competent Authority has drafted an analysis of the most appropriate risk management options (RMOA) in 2016. This RMOA identified several different risk

[1] See: https://echa.europa.eu/documents/10162/1a8a254c-bd4a-47b1-a091-99ae4a94a8c2

management options (e.g. binding occupational exposure limit value, specific RMOs within sectoral regulations for certain uses (e.g. biocides), identification for SVHC, restriction proposal). France launched a public consultation on the draft RMOA in July 2016 which ended on 31 October 2016.[2] One aim was to get clarification on the uses of the substance as intermediate.

Based on the substance evaluation by the Netherlands focusing on the concerns for consumers and general population, ECHA has decided on 6 October 2015 to request from the registrants further information regarding the registered substance and where relevant, asked the registrants to submit an update of the Chemical Safety Report[3]. The deadline for submitting the information to ECHA is by 13 October 2017. See also Annex I for the information required by the decision.

- Formaldehyde (reclassification of formaldehyde as Carc. 1B entered into force on 1 January 2016) is also included on the list of substances for which the Commission has launched a public consultation due to a possible restriction of CMRs (Categories 1A and 1B) in textile articles and clothing for consumer use according to article 68(2). The consultation ended on 22 March 2016[4].

- Formaldehyde being a skin sensitiser, is within the scope of RMOA to be prepared by Sweden concerning sensitisers in textile articles.[5]

- In addition, formaldehyde and certain formaldehyde releasers are regulated under other legislation such as the Cosmetic Product Regulation (Regulation (EC) No 1223/2009). Formaldehyde and some formaldehyde releasers are also covered in the review programme under the Biocidal Products Regulation (Regulation (EU) No 528/2012). Furthermore, the Scientific Committee on Occupational Exposure Limits has drafted a recommendation on occupational exposure limits for formaldehyde[6]. The public consultation of this document ended 17 February 2016.

[2] See: Consultation publique sur le rapport de l'Anses concernant la gestion des risques du formaldéhyde - Les consultations publiques du ministère de l'Environnement, de l'Énergie et de la Mer

[3] See: Formaldehyde - Substance evaluation - CoRAP - ECHA

[4] See: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299.

[5] See: PACT – RMOA and hazard assessment activities - ECHA

[6] See: https://circabc.europa.eu/sd/a/d44aedf4-8e61-47b4-96c6-91a6ff3139f7/2015-11-16v11%20REC-125%20Formaldehyde%20stage%2040.20.pdf

3. Approach

3.1. Task 1: Co-operation with FR and NL

ECHA contacted France to offer support in their RMOA development and agreed to assist in the review of the registration dossiers of formaldehyde with a view to determine the intermediate status of the registrations.

ECHA also contacted the Netherlands to discuss their approach to the ongoing Substance Evaluation work and following this contacted the lead registrant to inquire about their plans.

Comments received by ECHA during the call for evidence has been shared with France and the Netherlands, and the Commission.

3.2. Task 2: Formaldehyde releasers

To start identifying substances that are formaldehyde releasers, ECHA investigated the substances listed in an Annex V of the Cosmetic Product Regulation (EC) 1223/2009[7] (CPR); Annex V of CPR provides list of preservatives allowed in cosmetic products. Ten substances from this list were identified as formaldehyde releasers; these are in addition to formaldehyde, which is also in the Annex.

In addition, ECHA carried out a literature survey to identify additional formaldehyde releasers. An inventory of formaldehyde releasers is included in Table 6 of de Groot A.C. et al. (2009)[8] (36 substances: chemicals for which adequate clinical data are available to identify them as formaldehyde releasers beyond doubt, 7 substances: chemicals for which adequate clinical data are lacking to identify them as formaldehyde releasers beyond doubt). The ten substances from Annex V of the CPR are also included in the de Groot list.

In the first phase of screening, ECHA investigated those formaldehyde releasers listed in Table 6 of de Groot A.C. et al (2009) which have been registered under REACH.

The outcome of this screening (done on 18 May 2016) provided information on substances for which a registration dossier has been submitted to ECHA, including substance specific information on tonnage band registered, information on uses as described in the dossier and classification and labelling information.

In July 2016, ECHA launched a call for evidence to find out if other formaldehyde releasers than those identified in the first phase of screening exist and to gather more detailed information on uses for all the formaldehyde releasers already identified. Based on the information provided by responders to ECHA's call and additional information gathered from other sources (i.e. scientific articles, authorities, industry, registration dossiers), substances

[7] See: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:02009R1223-20150416 (The Annex V states that "All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %.".)

[8] See: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0536.2009.01582.x/epdf.

that are known formaldehyde releasers or possible formaldehyde releasers have been divided into three key groups:

1. formaldehyde releasers with intentional release of formaldehyde, i.e. substances used as biocides under the Biocidal Product Regulation and substances used as preservatives and included in Annex V of Cosmetic Product Regulation;

2. substances identified as formaldehyde releasers in the scientific literature or identified as such by the substances identified stakeholders; and

3. substances containing formaldehyde in their composition (as constituent of the substance or as impurity) used in various applications (potential formaldehyde releasers).

This report includes the feedback received through the call for evidence, information included in registration dossiers and more in-depth information from literature survey. In this report, substances falling under the Biocidal Product Regulation or the Cosmetic Product Regulation are listed but it has been assumed that uses covered by these regulations are not within the scope of this investigation.

In addition, in relation to potential formaldehyde releasing substances (group 3 above) ECHA screened the registration dossiers for any such potential formaldehyde releaser when the formaldehyde concentration > 0.1 % and where consumer uses are indicated.

4. Results of investigation

4.1. Formaldehyde

ECHA has liaised with both Member States (France and the Netherlands).

ECHA/France has investigated the intermediate status of formaldehyde and France has concluded that, especially for formaldehyde-based resins, this substance is used as intermediate/monomer (mostly transported isolated intermediates). France will update their draft RMOA based on comments received during their public consultation.

The Netherlands have not received any information at the date of publication of this report from the registrants and their plan is to consider further steps after the registrants have submitted the required information. After inquiry by ECHA the lead registrant informed that, they intend to submit information within the deadline, but not earlier.

4.2. Information on formaldehyde releasing substances and their uses

4.2.1. Identity of the substances

Formaldehyde releasers are a broad group of substances, with a common element, that they can release formaldehyde, whether intentionally or unintentionally, under different conditions. Information on these releasers have been gathered from other legislation (Cosmetic Product Regulation, CLP Regulation, Biocidal Product Regulation), from scientific literature described below and from registration dossiers. Comments from the call for evidence have also been taken into account. Formaldehyde is not part of this investigation.

4.2.2. Names and other identifiers of the substances

Tables 5-7 (in Annex 2) contain lists of formaldehyde releasers or potential formaldehyde releasers identified so far by ECHA. These substances have been listed in accordance to the criteria identified above for groups 1-3.

Table 5 (substances in group 1) provides substances that are identified as formaldehyde releases in the ongoing biocidal review (table extracted from formaldehyde releasing biocidal active substances included in the Commission delegated Regulation (EU) No 1062/2014 (the Review Programme Regulation)) and substances included in Annex V of the Cosmetic Product Regulation 1223/2009.

Table 6 (substances in group 2) includes substances identified as formaldehyde releasers that are included in Table 6 of de Groot A.C. et al. (2009)[9], and other substances identified as formaldehyde releasers from other sources (e.g. information from call for evidence, scientific literature etc.).

[9] See: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0536.2009.01582.x/epdf.

Table 7 (substances in group 3) is a list of substances registered under REACH containing formaldehyde included in their composition either as constituent of the substance or as impurity. The list provides also information on the uses of these substances as identified by registrants.

These lists of substances are not exhaustive lists for formaldehyde releasers or potential formaldehyde releasers. There are likely to be other formaldehyde releasers used in European Union and also used in articles imported in EU.

Concerning formaldehyde releasers identified by de Groot, A.C. et al. 2009, bronopol (CAS No 52-51-7) is not regarded as formaldehyde releaser according to the Member States Competent Authorities (see CA-Febr08-Doc.8.4 28th meeting of MSCAs for biocidal products). Moreover, comments received during the call for evidence indicate that another substance, i.e. ethylene urea (2-imidazolidone, CAS No 120-93-4) which was identified by de Groot, A.C. et al. as chemical for which adequate clinical data are lacking to identify them as formaldehyde releaser, is a formaldehyde scavenger. The purpose of this substance is thus to reduce residual formaldehyde by chemical reaction. Also N,N-dimethyl 4,5-dihydroxyethylene urea (CAS No 3923-79-3) was informed not to release formaldehyde (even though raw material used in the manufacturing process of the substance may contain formaldehyde as impurity, formaldehyde is not present in the final substance). Moreover, the draft RMOA by France identified the substance as a possible alternative to urea-formaldehyde resins in textile finishing.

4.2.3. Justification for grouping

The common element of formaldehyde releasers is formaldehyde and if formaldehyde is released in such concentrations, which might cause risks to human health, either from substances, mixtures or from articles.

4.2.4. Manufacture and uses

Manufacture and use information is mainly provided for substances which are registered to ECHA. Some additional data is included on uses from scientific literature reviewed.

The type and number of the registration dossiers of formaldehyde releasers submitted to ECHA, are listed in (in Annex 2).

Further screening was conducted with the substances where formaldehyde is mentioned as a constituent or an impurity.

The registration dossiers were investigated and the uses described in the dossiers are summarised in Table 9 (in Annex 2). Table includes also use information as provided by de Groot et al. (2009) from Danish Product Register Database (data on substances notified by less than three companies are not shown). Moreover, it should be noted that not all products need to be notified to the Danish Product Register (e.g. if used in products e.g. in clothes and textiles, if used in cosmetics or in metal working fluids).

The Danish Product Register Database provides more information on uses of these registered substances (de Groot et al. (2009)) than described in the registration dossiers. In addition, substance specific information received during the call for evidence has been included in the table.

General comments on the uses of formaldehyde releasers were received during the public consultation (see also summary of the comments in Annex 3):

- use in the production of fertilisers;
- certain resins and textile and leather auxiliaries based on formaldehyde are used to process textiles and leather: textile easy care finishing (non ironing), textile washing permanent finish, flame retardants coatings for technical textiles, cross linking in leather finishing, tanning with tanning resins and synthetic tanning agents;
- mixtures and articles containing many of the substances identified in the background note (to the call for evidence) are used in the production and maintenance of aerospace products. In addition to biocidal use, the substances are used as constituents of binding agents in primers, topcoats, adhesives and inks as well as in abrasive media for stripping organics and mechanical surface preparation. Other uses could be as a component in base polymers, binders, or chemical treatments of textiles, foams and insulation blankets;
- lysing agent for cells for in vitro diagnostic (IVD) reagents manufactured in compliance with Directive 98/79/EC;
- formaldehyde is used as a constituent in the manufacture of a purchased material (polyvinyl formal – PVF) for critical dublex bonding system used on site[10];
- in photochemicals and pressroom chemicals: e.g. corrosion/alkali, matting agent in coatings, solvent in certain photochemicals and to solve colour developers, and
- formaldehyde (as resorcinol-formaldehyde-latex dip or resorcinol-formaldehyde precondensate) is being used in the production of tyre cord (textile reinforcement material for tyres, e.g. made of rayon, polyester, nylon or aramid fibers).

The French draft RMOA (2016) provides information e.g. on major applications for formaldehyde-based resins. According to the draft RMOA, 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)

[10] According to Fitzhugh A. et al. (1953) a major application of PVF is in wire enamel, where cross-linking occurs. Solutions are also used for solenoid bonding and metal priming. Other applications include injection molding, calendering, reinforcement of more brittle resins, thermal adhesives for metals, and plasticized compositions. One company information on uses can be found from its website: ingredient in PVA based wire enamels which require excellent resistance to transformer oil. These enamels provide outstanding toughness, flexibility and abrasion resistance.

Substance is also used in combination with other resins to produce adhesives and surface coatings. (see: https://www.dorfketal.com/industry-solutions/insoform-and-insothane/insoform-polyvinyl-formal)

- 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 fertilizers in agriculture and non-agricultural sector.

According to a study conducted by ICF International (2013) in the context of article 68(2) to REACH[11] the main intermediate applications of formaldehyde-based resins are in the construction, automotive, aircraft, clothing and healthcare industries.

In consumers/general public applications, formaldehyde is used (Anses, 2011, as referred in draft RMOA, France (2016)):

- As a preservative and biocidal agent in detergent, disinfectant and cleaning agent

[11] See: http://ec.europa.eu/DocsRoom/documents/13035/attachments/1/translations

- As a preservative in cosmetics
- In building and insulating material (such as UF or PF foam insulation)
- In wood-based panels
- As a binding agent in paints and lacquers
- As a binding agent in adhesives
- In human food (food additive and technological auxiliary)
- In vaccines and medicines

ICF International (2013) analysed that, in the region of the 7,500 tonnes of formaldehyde (about 7000 tonnes in furniture, about 300 in automobiles/cars, and between 200 and 300 tonnes in mattresses) of formaldehyde per annum is estimated to be contained in consumer articles being commercialised in the EU.

An overview of uses identified by registrants is provided in Table 7 (in Annex 2) for registered substances with formaldehyde in their composition. Uses are reported on the basis of the life cycle stage (i.e. use at industrial site, use by professional workers, use by consumers).

4.2.5. Uses advised against by the registrants

No uses advised against have been included in lead registrants' registration dossiers for registered formaldehyde releasers.

5. Discussion related to formaldehyde and formaldehyde releasers

The following sections pull together the information gathered during the two tasks detailed above and other relevant information gathered on formaldehyde and formaldehyde releasers to give an overview relevant for decision making by the Commission.

5.1. Hazard

5.1.1. Classification and labelling

Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) and Classification and labelling in classification and labelling inventory/ Industry's self classification(s) and labelling

Classification and labelling of formaldehyde has been revised (new classification entered into force on 1 January 2016) to: Carc. 1B, Muta. 2, Acute Tox. 3 (oral), Acute Tox. 3 (dermal), Acute Tox. 3 (inhalation), Skin Corr. 1B and Skin Sens. 1. The most significant change is that now formaldehyde is classified as carcinogenic, category 1B. The specific concentration limits for classification of a mixture containing formaldehyde are the following: Skin Irrit. 2; H315: 5% ≤ C < 25 %, Skin Sens. 1; H317: C ≥ 0,2 %, Eye Irrit. 2; H319: 5 % ≤ C < 25 %, STOT SE 3; H335: C ≥ 5 % and Skin Corr. 1B; H314: C ≥ 25 %. For the carcinogenicity no specific concentration limit is given thus the general concentration limit in the CLP Regulation will apply: category 1B carcinogen C ≥ 0.1 %.

Notes 8 and 9 of 10th adaptation to technical progress (ATP) to the CLP regulation include provisions for classification of substances and mixtures that release formaldehyde. Substances or mixtures releasing formaldehyde are classified as carcinogen if concentration of releasable formaldehyde is ≥0.1 % (note 8). They are classified as mutagen if concentration of releasable formaldehyde is ≥1 %. In addition, substances containing formaldehyde as a impurity ≥0.1 % may also be classified as a carcinogen.

ECHA's Committee for Risk Assessment has recently also adopted opinions on proposals for harmonised classifications for three formaldehyde releasers (see Table 10 in Annex 2). RAC states that where data on [substance] are lacking data on the hydrolysis products formaldehyde [and other hydrolysis products depending of the substance] were used. The classification according to the opinions of RAC for all three substances is Carc. 1B and Skin Sens 1, including other substance specific hazard classifications (e.g. Aquatic Chronic 2 (except for MBM)).

The classification and labelling (harmonised classification and labelling as in Annex VI of CLP Regulation) for substances in Table 6 and Table 7 is included in Table 11 of Annex 2. ECHA has also received more than hundred thousand self-classifications from industry. They are not included in this report. The concentration of formaldehyde (as constituent or impurity) for substances included in Table 7 (registered substances with formaldehyde in their composition) is >0.1 % only in a limited number of cases and for substances only registered for industrial and/or professional uses.

5.1.2. Human health hazard assessment

5.1.2.1. Carcinogenicity

The Committee for Risk Assessment (RAC) stated when provided its opinion on classification and labelling proposal for formaldehyde (adopted 30 November 2012)[12] that formaldehyde should be as carcinogen Carc. 1B, H350: May cause cancer. RAC also stated that the route(s) for exposure should not be stated in the hazard statement as it is not proven that other routes besides inhalation can be excluded. According to RAC formaldehyde is a local acting genotoxic carcinogen. In addition, RAC noted that the database for low-dose effects is limited and that the data does not allow a firm conclusion on a threshold-mode of action or the identification of threshold.

In its opinion proposing harmonised classification and labelling (RAC, 2012) RAC states that there is limited evidence of carcinogenicity in humans mainly from the positive association of nasopharyngeal tumours in industrial cohorts, but that there is sufficient evidence of carcinogenicity from animal studies.

SCOEL in its opinion has recommended an Occupational Exposure Limit Value (OEL) of 0.3 ppm (8h TWA) with a STEL of 0.6 ppm. This is based on their assessment that formaldehyde is a genotoxic carcinogen, for which a mode-of-action based limit value can be derived. No OEL (indicative or binding) based on this recommendation has been adopted yet by the Commission.

5.1.2.2. Sensitisation

Formaldehyde is a known skin sensitiser, which has the classification: Skin Sens 1; H317. This classification starts with the concentration: C≥0.2 %. Patch test results with the European baseline series, and country specific (11 European countries) or department specific (39 departments) additions to it, showed that the prevalence of sensitisation to formaldehyde varied from 1.2 – 5.9 %. In addition, some formaldehyde releasers are also included in this list, e.g. Quaternium-15: prevalence varied from 0.1-3.2% (among EU 8 countries), diazolidinyl urea: 0.8-1.8% (among EU 7 countries) and imidazolidinyl urea: 0.4-1.3% (among EU 8 countries). In addition the prevalence to p-tert-butylphenol formaldehyde resin varied from 0.5-1.6% (among 10 EU countries), however the article does not state if the reason for sensitisation is formaldehyde (Uter, W. et al. 2012).

5.1.2.3. DNEL setting

France is using the following DNELs in its risk characterisation:

- the worker long-term DNEL for inhalation is 0.3 ppm (0.37 mg/m^3) and
- the worker short-term DNEL for inhalation is 0.6 ppm (0.75 mg/m^3).

The DNELs are derived based on the studies by Lang et al. (2008) and Mueller et al. (2013) as referred in the RMOA. These values match the recommendation of SCOEL for an OEL.

[12] See: https://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling?diss=true&search_criteria_ecnumber=200-001-8&search_criteria_casnumber=50-00-0%2C+500-00-0&search_criteria_name=Formaldehyde

RMOA states that prevention of irritant effects of formaldehyde is considered protective of its carcinogenic effects.

No DNEL for effects on the consumer has been derived, however, if a DNEL is appropriate it could be expected to be lower than the DNEL for workers. An indoor air quality guideline value of 0.1 mg/m^3 is available (see section on Summary of existing legislative requirements: indoor air quality).

5.2. Exposure assessment

5.2.1. General discussion on exposure and releases

5.2.1.1. Exposure to workers

France and the Netherlands have jointly evaluated formaldehyde under substance evaluation scheme. The workers part of the evaluation (evaluated by FR) concluded that there is a concern for workers in certain activity sectors. Consequently, France has drafted a risk management option analysis (draft RMOA, 2016) for formaldehyde covering professional and industrial uses for which a risk for workers has been demonstrated or is anticipated. The draft RMOA, which was under public consultation by 31 October 2016, provides information also on some other substances that might release formaldehyde, such as resins (urea-formaldehyde (UF) resins, melamine-formaldehyde (MF) resins, phenol-formaldehyde (PF) resins and polyacetal resins (polyoxymethylene – POM)). According to Formacare (referred in the draft RMOA) UP, MF and PF resins are the three major commercially-used resins formulated with formaldehyde and the primary use of formaldehyde (around 56 % of world consumption). In addition, formaldehyde is an intermediate in the production of synthesis of industrial chemicals and plastics. French draft RMOA lists the following substances where formaldehyde is used in the chemical synthesis as a starting material: diphenylmethane diisosyanate (MDI), 1,4-butanediol (BDO), pentaerythritol, polyols hexamethylenetetramine (HTMA – hexamine) and as an intermediate in the production of paraformaldehyde (PFA).

In the risk characterisation, France is using exposure data from the 2014 substance evaluation report (SEv, 2014 (not published yet)), which was based on registrants' data from 2013 and by the French Colchic database. The exposure data covers also processes that release formaldehyde.

The sectors where a risk caused by formaldehyde is indicated are described in tables 21 and 22 of the draft RMOA and referred in Table 1 and Table 2 below.

Table 1. SECTORS AT RISK DEPENDING ON MONITORED OR MODELLED FORMALDEHYDE CONCENTRATIONS FOR SHORT AND LONG TERM EXPOSURE FROM 2013 REGISTRANT CHEMICAL SAFETY REPORT (TABLE 21 OF THE DRAFT RMOA)	
Long-term exposure	**DNEL 0.3 ppm**
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**
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)

Table 2. OCCUPATIONAL SECTORS AT POTENTIAL RISK (EXPOSURE DATA FROM FRENCH COLCHIC DATABASE FOR THE PERIOD 2007-2013) (TABLE 22 OF THE DRAFT RMOA)	
Long-term exposure	**DNEL 0.3 ppm**
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**
Activity sector at risk (as cited in COLCHIC)	Public health services Private health services

One example of occupational exposure studies is conducted by Viegas S. et al. (2010) who studied genotoxic effects in occupational exposure to formaldehyde in anatomy and pathology laboratories and formaldehyde-resins production. It is to be noted that anatomy and pathology laboratories typically use formaldehyde, which is in biocidal use falling under Biocidal product Regulation product type (PT) 22: Embalming and taxidermist fluids used for the disinfection and preservation of human or animal corpses, or parts thereof.

In this study, both time-weighted average concentrations (TWA_{8h}) (by personal sampling) and ceiling concentrations (by Photo Ionization Detection (PID) equipment with simultaneously video recording) were measured in the working places. One specific aspect that the authors noted, is that health effects (cancer) linked to formaldehyde exposure are more related with peaks of high concentrations than with long time exposure at low levels. In this study, the exposure to formaldehyde in formaldehyde-resins production (resin not defined) were within the range of 0.20-0.22 (mean 0.21) ppm (TWA_{8h}) and the ceiling concentrations were within the range of 0.003-1.04 (mean 0.52) ppm.

5.2.1.2. Exposure to consumers

Information from the substance evaluation

The substance evaluation for formaldehyde prepared by the Netherlands covering consumer exposure and general public, concluded that there is a need to request further information from the registrant(s). As a result of the substance evaluation, ECHA decided to request specific information from the registrants (see details in Annex 1). The information requested covers the lifecycle of formaldehyde (excluding environmental aspects, as the environmental related endpoints of the substance were not evaluated by France and the Netherlands). Due to this the information required relates also information on formaldehyde releases and emissions of formaldehyde from different materials where the origin of the formaldehyde is e.g. from resins. The information required covers e.g. a review of literature data including registrant(s)' own data on the emission rates (in $\mu g/m^2/h$), comprising time-dependency (where available) for the major sources and their relative contribution to the total indoor air concentration of formaldehyde. The sources considered by the registrant(s) shall include, but need not be limited to the following sources:

i. building/construction materials such as wood based plate materials for ceiling and flooring and mineral wool;

ii. furniture and other urea formaldehyde (UF) pressed wood products like hardwood plywood panelling and fiberboard;

iii. paints;

iv. wallpapers;

v. textiles such as curtains, carpets;

vi. cleaning agents; and

vii. combustion sources such as cooking.

The sources (i), (ii), (iv) and (v) are of interest in regards substances that release formaldehyde within this report. Formaldehyde emitted from paints and cleaning agents normally is due to biocidal uses of formaldehyde or formaldehyde releasers and are covered by the Biocidal Products Regulation. Formaldehyde originated from combustion sources such as cooking is outside the scope of this investigation.

The registrant(s) has to submit the required information by 13 October 2017. The Netherland will finalise the substance evaluation after receiving the information.

Due to the work conducted already by France and the Netherlands and as further information is expected in 2017 from registrant(s), this report will only provide some general discussion on emissions and releases, and especially releases to air and not releases to skin.

Indoor air research

The uses of formaldehyde and formaldehyde releasers and the sources of emissions and releases already indicated in the substance evaluation and ECHA decision (such as building and construction materials, furniture, plywood panelling and fibreboard, wallpapers, textiles and carpets) for which further information is needed indicate already in which compartments formaldehyde can be released. Formaldehyde may be released to indoor air, whether in offices, homes, schools, hotels, shopping malls, restaurants, bus/train/ship/car interior, mobile homes etc.

In 2007, the Scientific Committee on Health and Environmental Risks (SCHER) has provided an opinion on risk assessment on indoor air quality. In its conclusion, SCHER considers formaldehyde to be one of the compounds of concern because it has caused adverse health effects as indoor pollutant or have a high potential to cause them.

Salthammer T. et al. (2010) has made a literature review and summarised the current (at that time) status of indoor-related formaldehyde research. The article provides information on indoor related applications of formaldehyde in the past and present summarised by a number of authors:

- Wood-based products (particle board, oriented-strand board (OSB), high-density fiber board (HDF), mediumdensity fiber board (MDF), plywood)

- Cork products (flooring materials)
- Insulation materials made of UF foam, mineral wool, or glass wool
- Paper products
- Coating materials, paints, and lacquers containing formaldehyde as preservative
- Textiles
- Cleaning and caring products
- Disinfectants and preservatives
- Photoprocessing chemicals
- Cosmetics.

The following Table 3 (Table 10 of Salthammer et al. (2010)) is a compilation of indoor-related formaldehyde emissions studies. Table provides emission rates of different building products and the rates are cited as they appear in the references, due to the fact that comparison of product emission rates was considered difficult because different methods and units are used. Emission rates are expressed in $mg/m^2/h$ or as a chamber concentration (ppm, ppb, mg/m^3) in the case of the steady state. It should be noted that some of the studies are rather old, thus not always representing the current situation where emissions from products have been regulated or limited by voluntary measures.

Table 3 COMPILATION OF INDOOR-RELATED FORMALDEHYDE EMISSION STUDIES (AS REFERRED BY SALTHAMMER ET AL., 2010)

Table 6. Compilation of Indoor-Related Formaldehyde Emission Studies[a]

material	T (°C)	r.h. (%)	L (m^2 m^{-3})	n (h^{-1})	HCHO emission	comment	year[ref]
chipboard	22	35	1.7	0.5	0.70 ppm		1975[230]
particle board	22	30	1.6	0.2	0.40 ppm		1980[234]
	27	60	1.6	0.2	1.70 ppm		
	27	30	1.6	0.5	0.80 ppm		
	22	60	1.6	0.5	0.90 ppm		
particle board	25	50	0.131−0.426	0.25−0.50	0.095−0.29 ppm	10 samples	1987[233]
OSB	23	45	1.0	1.0	0.01−0.09 ppm	31 samples (median: 0.04 ppm)	2008[246]
solid wood	23	45	1.0	1.0	2−9 ppb	beech, Douglas fir, oak, spruce, pine	1996[43]
UF wood products (bare)	22	50	0.46	1.0	8.6−1580 μg m^2 h^{-1}	19 samples (median: 164 μg m^2 h^{-1})	1999[73]
UF wood products (bare)	27	50	0.46	0.3	6.8−1170 μg m^2 h^{-1}	19 samples (median: 158 μg m^2 h^{-1})	
PF wood products (bare)	22	50	0.46	1.0	4.1−9.2 μg m^2 h^{-1}	4 samples	
PF wood products (bare)	27	50	0.46	0.3	9.5−13 μg m^2 h^{-1}	4 samples	
UF wood products (coated)	22	50	0.46	1.0	<2.7−460 μg m^2 h^{-1}	14 samples (median: 8.6 μg m^2 h^{-1})	
UF wood products (coated)	27	50	0.46	0.3	4.6−1300 μg m^2 h^{-1}	14 samples (median: 15 μg m^2 h^{-1})	
decorative laminates	22	50	1.83	1.0	4.0−51 μg m^2 h^{-1}	3 samples	
cabinetry materials	23	50	1.9	5.7	8−470 μg m^2 h^{-1}	particle board, hard board, plywood	2002[243]
particle board (18 mm)	25	50	2.16	0.5	0.45 mg m^2 h^{-1}	7 days after sample installation	2006[247]
MDF (18 mm)	25	50	2.16	0.5	0.33 mg m^2 h^{-1}	7 days after sample installation	
laminate	25	50	2.16	0.5	0.03 mg m^2 h^{-1}	7 days after sample installation	
engineered flooring	25	50	2.16	0.5	0.04 mg m^2 h^{-1}	7 days after sample installation	
floor covering: natural wood	23.2	n.d.	n.d.	n.d	288 μg m^2 h^{-1}	1 h exposure to 750 ppb ozone	2009[256]
floor covering: wood-based	23.2	n.d.	n.d.	n.d.	31 μg m^2 h^{-1}	1 h exposure to 750 ppb ozone	
floor covering: PVC[b]	n.d.	50	505	514−686	<5−18 μg m^2 h^{-1}	new building (mean: 9 μg m^2 h^{-1})	2007[250]
floor covering: parquet[b]	n.d.	50	505	514−686	<5−10 μg m^2 h^{-1}	new building (mean: 7 μg m^2 h^{-1})	
ceiling[b]	n.d.	50	505	514−686	5−96 μg m^2 h^{-1}	new building (mean: 42 μg m^2 h^{-1})	
walls[b]	n.d.	50	505	514−686	<5−11 μg m^2 h^{-1}	new building (mean: 7 μg m^2 h^{-1})	
mineral wool	23	45	1.0	1.0	0.02−0.10 ppm	5 samples (4 samples <0.05 ppm)	1993[249]
fiberglass products	23	50	0.87−1.04	1.0	16−32 μg m^2 h^{-1}	3 samples	1999[73]
wall coverings	23	45	1.0	1.0	0.05−0.035 ppm	10 samples (median: 0.015 ppm)	1993[70]
carpet	23	45	0.4	0.5	8−15 μg m^{-3}	4 samples, 24 h values	2008[251]
latex paint	n.d.	18−58	flow chamber (2.5 L/min)		0.13−6.29 μg h^{-1}	11 samples exposed to ozone	1995[88]
paints	22	50	1.04	1.0	326−663 μg m^2 h^{-1}	3 products, initial emission	1999[73]
paints	22	50	1.04	1.0	8.1−9.8 μg m^2 h^{-1}	3 products, final emission	
carpet	23	50	n.d.	7	4−30 μg m^2 h^{-1}	4 samples exposed to ozone	2006[85]
household products	21−23	36−55	n.d.	0.95−1.08	8.2−23.7 ppb	3 products exposed to ozone	2006[83]
textiles	22	50	7.05	1.0	107 μg m^2 h^{-1}	permanent-press T-shirts (unwashed)	1999[73]
					42 μg m^2 h^{-1}	permanent-press T-shirts (washed)	
temporary housing units	22−25	49−58	n.d.	0.15−0.39	164−266 μg m^2 h^{-1}	morning (unoccupied)	2008[307]
	26−30	46−49			257−347 μg m^2 h^{-1}	afternoon (unoccupied)	
photocopy machines	26−31	30−35	1[c]	2.0	<500−2600 μg h^{-1}	4 dry-process photocopy machines	1996[441]
building products	23	30−50	8.2−14.7	12	5.5−40.6 μg m^2 h^{-1}	14 products exposed to ozone	2007[71]
burning of incense	23	50		0.5	ca. 20−300 μg m^{-3}	3 sticks in 18.26 m^3 chamber	2004[260]
					ca. 300−1700 μg g^{-1}	10 products tested	
wood burning					180−710 mg kg^{-1}	4 samples (birch) tested in wood stove	2002[55]
wood burning					599−1165 mg kg^{-1}	oak, pine, eucalyptus	2001[56]
cigarette smoking	20−25	45−55		0.022	234.1 μg m^{-3}	average of 8 commercial cigarettes	2004[98]
experimental cigarettes					30−57 μg $cigarette^{-1}$	13 cigarettes with added saccharides	2006[261]
formaldehyde in breath					1.2−72.7 ppb	median: 4.3 ppb (deep lung portion)	2005[105]

[a] The emission values are presented as they appear in the references. [b] Measured on site by use of the FLEC. [c] Units per volume.

T=temperature, r.h.=relative humidity, L=surface-to-volume loading rate, n=air exchange rate

Salthammer T. et al. (2010) concluded that an evaluation of recent emission studies and indoor surveys has demonstrated that the situation has improved due to the progress made over recent decades regarding indoor products with reduced emissions. The average exposure of the population to formaldehyde seems to be between 20 µg/m^3 and 40 µg/m^3 under normal living conditions. Authors however noted that these average concentrations do not take into account the higher exposure, which may result from new buildings or special indoor conditions, peak concentrations, and individual cases. Authors also conservatively estimate that additional sources, such as outdoor air, indoor chemical reactions (e.g. possible increase of formaldehyde concentration in the presence of ozone), candles, cooking, gas heaters etc. contribute 10 – 50 % to formaldehyde indoor concentration levels.

Salthammer T. and Mentese S. (2008) have studied aldehydes in test chambers. The study was conducted to compare the analytical techniques for the determination of aldehydes in test chambers. However, the results of the study showed also that with the test cabin even though built with low-emitting materials (products (i.e. textile carpet, acrylate based carpet adhesive, wallpaper adhesive, water-based primer and plaster, a side board with lacquer) were commercially available[13]) it was not possible to achieve formaldehyde concentrations lower than 20 µg/m^3. An increase of the formaldehyde concentration up to 69 µg/m^3 were observed when the test cabin was equipped with carpet, carpet adhesive and a side board made of lacquered particle board.

In Czech Rebublic, Böhm M. et al. (2012) have studied formaldehyde emissions from a variety of solid wood, plywood, blockboard and flooring products using the European small-scale chamber (EN 717-1) and gas analysis (EN 717-2). The study describes the formaldehyde resins used. The concentrations measured ranged from 0.006 mg/m^3 (engineering flooring with PVAc) to 0.048 mg/m^3 (painted birch blockboard) and decreased by the end of the measuring period.

Release of formaldehyde from textiles has been surveyed in Europe (JRC, 2007), but this is not reported further in this document as the Commission is considering to restrict CMR substances (formaldehyde being part of the proposal) in textiles and also Sweden is analysing risk management options for sensitisers (including formaldehyde) in textiles.

Indoor air concentrations of formaldehyde and emissions from products have been studied in some non-European countries, like in Canada (studies reviewed by Health Canada, 2005), in China (e.g. Huang L. et al. (2013), Lee S-C. et al. (2002) and Cheong K.W. and Chong K.Y. (2001)), and different reviews have been made (e.g. review of the existing published literature on indoor air quality (IAQ), ventilation and building related health problems in schools by Daisey J.M. et al. (2003)). In USA, the U.S. Consumer Product Safety Commission (CPSC) has made a booklet, which provides general information on formaldehyde releases and potential impact of formaldehyde on indoor air quality.[14] These studies and reports are not described in this report, as the aim has been to gather information from the European situation.

5.2.1.3. Humans exposed via the environment

Based on the data provided in the registration dossiers of formaldehyde, the exposure of humans via the environment is not a relevant route of exposure due to high biodegradability (readily biodegradable (99% degradation after 28 d)) and low bioaccumulation potential of the substance (Log Pow = 0.35). However, there are certain outdoor sources of formaldehyde, like formaldehyde as a natural compound, atmospheric reactions (e.g. alkene-ozone reactions) and outdoor combustion (e.g. combustion of wood, automobile exhaust gas) and industrial formaldehyde releases (Salthammer T. et al. (2010)). These have not been further discussed in this report.

[13] Even though not explicitly mentioned in the report, the assumption is that the study was conducted in Germany and the products bought from German market

[14] https://www.cpsc.gov/PageFiles/121919/An-Update-On-Formaldehyde-725.pdf

6. Summary of the existing legal requirements

EU regulation addressing workers exposure and emissions to environment are described in in the draft RMOA for formaldehyde prepared by France.

6.1. Biocidal Product Regulation (EU) No 528/2012 (BPR)

According to the Biocidal Product Regulation (Regulation (EU) No 528/2012) all biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved. However, a transitional period is granted to existing active substance and product types included in the Review Programme. Hence, certain biocidal products containing existing active substance can be made available on the market and used in EU even until they are approved. Within the meaning of the BPR, a biocidal product is a product intended to protect humans, animals, materials or articles against harmful organisms like pests or bacteria.

Article 2(2) of the BPR states that the Regulation shall not apply to biocidal products or treated articles that are within the scope of different instruments mentioned in that article, e.g. Cosmetic Product Regulation (EC) No 1223/2009 and Directive 2009/48/EC on the safety of toys.

Formaldehyde is listed in Annex II to the Review Programme Regulation to be evaluated by Germany for the product types (PT): PT2 (Disinfectants and algaecides not intended for direct application to humans or animals), PT3 (Veterinary hygiene) and PT22 (Embalming and taxidermist fluids). The description of the product types are listed in the Annex V to the BPR[15].

Concerning formaldehyde releasers the Member State Competent Authorities for the implementation of BPR agreed (CA-March 15-Doc.5.1-Final (Revised on 23 June 2015)) on the definition of 'active substance releaser'. Active substance releasers are defined as substances that upon use release active substances, hence substances which have a biocidal activity. For such substances, no other precursor is required, the reaction is taking place under certain conditions and not necessarily at the place of use. Both the (active) substance released and the substance releaser contribute to the definition of the active substance and in the context of BPR the name of the active substance will be the combination of the names of the substance released and of the substance releaser (e.g. Formaldehyde released from N,N'-methylenebismorpholine). Annex II of the document provides a non-exhaustive list of substances falling under the definition for active substance releaser, including 12 formaldehyde releasers. These substances are listed in the Review Programme Regulation to be evaluated for the supported PTs (see Table 5 in Annex 2).

Before other formaldehyde releasers than those listed in the Review Programme can be made available on the market within the context of the BPR, the active substance/releaser need to be approved and the biocidal product authorised.

[15] Description on product types: Product-types - ECHA.

The uses falling under the specific product types of the 12 formaldehyde releasers that are covered by the BPR will be out of the scope of this investigation. However, if there are other uses of these substances not supported by the BPR, these will be described in this report.

6.2. Cosmetic product regulation (EC) No 1223/2009

Regulation (EC) No 1223/2009 on cosmetic products is the main regulatory framework for finished cosmetic products when placed on the EU market. Annex V to the regulation provides list of preservatives allowed in cosmetic products. Within the meaning of the regulation preservatives are defined as being substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product. Other preservatives that are not listed in Annex V and those that are listed there but not used in accordance with the conditions in that Annex cannot be used in cosmetic products. The Annex specifically states that all finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05%. The Annex does not exactly say which of those substances listed are formaldehyde releasers, but they are included in the Table 5 (in Annex 2) of this report.

Substances that are Carcinogenic, Mutagen and Toxic for Reproduction (CMR) are subject to special provisions in the Cosmetic Product Regulation. Article 15 states that CMR substances, of category 1A or 1B under part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP) shall be prohibited with the possibility of providing an exemption to the prohibition under strict conditions. Annex II of the Cosmetic Product Regulation contains the list of substances prohibited in cosmetic products. The Commission is working to amend the Annex II of the Regulation by adding all recently classified CMRs, including formaldehyde. Whether all uses of formaldehyde in cosmetics will be prohibited is under consideration. The plan is to have the amended list adopted by end of 2017. Formaldehyde releasers are not within the scope of that amendment.

Restrictions under REACH do not apply to cosmetic products with regards to human health risks (art 67(2) to REACH), however if substances in cosmetic products cause risks to the environment, restrictions under REACH can be used to control the risks.

6.3. REACH Regulation (EC) No 1907/2006

Under REACH Regulation (EC) No 1907/2006 it is possible to pose restrictions on substances which cause unacceptable risks to the human health or the environment, which cannot be adequately controlled. Currently there are no restrictions on formaldehyde or formaldehyde releasers other than the general restriction entry 3 of Annex XVII covering liquid substances or mixtures with specific hazard classifications (it is not known if the substances under this investigation have been used in the applications within the scope of that restriction). However, as formaldehyde is now classified as carcinogenic category 1B, the Commission has the possibility to restrict the placing on the market of formaldehyde for supply to the general public under entry 28 of Annex XVII according to article 68(2) to REACH. In the draft amendment to the Annex XVII (inclusion of CMR substances in Appendixes to restriction entries 28 to 30) the Commission is proposing not to include formaldehyde within the scope of the amendment due to the work carrying out in ECHA on formaldehyde and formaldehyde releasers. In case the classification and labelling as proposed in the opinions of the Committee for Risk Assessment (RAC) for several substances that release

formaldehyde (see section Classification and labelling) will be adopted, the same option on restriction could be applied to these substances.

The Commission has drafted a restriction proposal under article 68(2) on CMR category 1A and 1B substances in textiles, which has been under public consultation[16]. Formaldehyde is included in the lists of substances under the proposal. Commission has also published a scoping study for the application of Article 68(2) of REACH to construction articles containing CMR substances with likelihood of consumer exposure[17]. Release of formaldehyde from construction articles has been investigated. In addition, Sweden is preparing a risk management option analysis (RMOA) on skin sensitising substances in textile articles[18].

6.4. Textile Regulation (EU) No 1007/2011

Textile Regulation (EU) No 1007/2011 on fibre names and related labelling and marking of the fibre composition of textile products provides e.g. general obligation to state the full fibre composition of textile products and a requirement to indicate the presence of non-textile parts of animal origin. The regulation does not have any provisions on health or environment safety of chemicals used in textiles.

However, several other legislation provides some requirements on specific substances in textiles. REACH Regulation is described above. Textile as articles containing dangerous chemicals is regulated by REACH, see the case of nonylphenol ethoxylates. Textiles need to be in line with the General product safety regulation. Textiles in toys are regulated with the toy safety legislation (see below).

6.5. Directive 2009/48/EC on the safety of toys

Directive 2009/48/EC on the safety of toys aims to ensure a high level of protection of children. Annex II of the directive provides particular safety requirements. Part III (Chemical properties) of this Annex states that toys shall comply with the relevant Community legislation relating to certain categories or products or to restrictions for certain substances and mixtures. Moreover, the same part prohibits the use of CMR category 1A, 1B or 2 substances use in toys, in components of toys or in micro-structurally distinct parts of toys. However, some exceptions to this provision exists, e.g. that these substances and mixtures are inaccessible to children in any form, including inhalation.

During the call for evidence some comments were received on the use of formaldehyde releasers in toys and more specifically that certain standards (EN 71-4:2013, EN 71-5:2013-08, EN 71-7:2014) provide limit values for formaldehyde releasers used in toys.

6.6. Construction Products Regulation (EU) No 305/2011

The construction product regulation (EU) No 305/2011 (CPR) aims to protect general population, but also workers and the environment. The regulation states that when assessing the performance of a construction product, account should also be taken of the

[16] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299.

[17] http://bookshop.europa.eu/en/take-two-pbKH0116253/

[18] PACT – RMOA and hazard assessment activities - ECHA

health and safety aspects related to its use during its entire life cycle. However, the Construction Products Regulation does not specifically regulate chemicals in construction products as it addresses to REACH in terms of restriction of substances in construction materials. French draft RMOA (2016) describes the EC wood-based panels regulation and standards for emissions from wood-based panels, but also voluntary action taken by the European Panel Federation (EPF) in more details (see voluntary agreement section below). The Table 14 of the draft RMOA provides board classes and corresponding limit values set up by EN 717 (see Table 4 below).

Table 4. BOARD CLASSES AND CORRESPONDING LIMIT VALUES SET UP BY EN 717

Test Method	Board Class	Limit Value
EN 717-1 EN 120	E1 particleboard, MDF and OSB	≤ 0.1ppm ≤ 8mg/100g
EN 717-1 EN 717-2	E1 plywood	≤ 0.1ppm ≤ 3.5 mg/(h m²)
EN 717-1 EN 120	E2 Particleboard, MDF, OSB	> 0.1ppm > 8 - ≤ 30 mg/100g
EN 717-1 EN 717-2	E2 Plywood	> 0.1ppm > 3.5 - ≤ 8.0 mg/(h m²)

Source: French draft RMOA (2016)

The Swedish Chemical Agency (KEMI) has recently published a report "Hazardous chemicals in construction products, Report 4/2016)[19] under an assignment to investigate the need to draft national regulations regarding hazardous chemicals in construction products in order to reduce children's level of exposure. Formaldehyde was one of the substances under investigation.

6.7. Voluntary agreements

According to Formacare (2016), the wood panel industry has developed a voluntary European standard (E1) based on the WHO recommendation for indoor air levels of formaldehyde (WHO recommendation: 0.1 mg/m^3). Although wood products still emit formaldehyde, the E1 label ensures that these products remain significantly below the WHO guideline. The voluntary efforts of the wood panel industry have helped lower the concentration of formaldehyde in resins from around 100 mg/100 g of panels in 1975, to less than 8 mg/100 g nowadays; that is from 0.1 % to 0.008 %.

6.8. Indoor air quality

In the EU there is no harmonised limit value for formaldehyde in indoor air.

WHO (2012) has reviewed and evaluated scientific evidence on formaldehyde and has provided guidelines for indoor air quality for 30-minutes average concentration: 0.1 mg/m^3 (critical end-point being sensory irritation). According to WHO, this short-term guideline will

[19] See: http://www.kemi.se/global/rapporter/2016/report-4-16-hazardous-chemicals-in-construction-products.pdf

also prevent effects on lung function as well as long-term health effects, including nasopharyngeal cancer and myeloid leukaemia.

The study by Lang I. et al. (2008) was used by WHO to derive the NOAEL of 0.63 mg/m^3 (conjunctival redness and increases in eye blinking frequency at a four-hour exposure), which was adjusted using an assessment factor of 5 derived from the standard deviation of nasal pungency (sensory irritation) threshold, leading to a value of 0.12 mg/m^3, which has been rounded down to 0.1 mg/m^3.

The air quality guideline value of 0.1 mg/m^3 is the same as provided by WHO in 2001 (Air Quality Guidelines for Europe 2000).

In the European Index project "Critical appraisal of the setting and implementation of indoor exposure limits in the EU" (Joint Research Centre, 2005), an assessment of risks of formaldehyde was conducted and recommendation of the limit value for indoor air provided. The report stated that because of its high chemical reactivity, formaldehyde is the most important sensory irritant among the chemicals assessed in the present report. Due to being ubiquitous pollutant in indoor environments and to the increasing evidence indicating that children may be more sensitive to formaldehyde respiratory toxicity than adults, it is considered a chemical of concern at levels exceeding 1 µg/m^3, a concentration more or less corresponding with the background level in rural areas. The report noted that the WHO air quality guideline value should be regarded as hazardous for susceptible individuals (children) when evidence exist that concentrations are maintained over prolonged period.

The review by Arts J. et al. (2008) concluded that the indoor air level of 0.1 ppm (0.12 mg/m^3) of formaldehyde as indicated by Appel K. et al. (2006) can be considered safe and appropriate. This was different from the conclusion of the studies used in the European Index project. In particular the review raised concerns if the correct point of departure/dose descriptor had been used and the appropriateness of the assessment factors applied.

Wolkoff P. and Nielsen G. (2010) evaluated non-cancer effects of formaldehyde and relevance for setting an indoor air guideline and concluded that an air quality guideline of 0.1 mg/m^3 (0.08 ppm) is considered protective against both acute and chronic sensory irritation in the airways in the general population.

It is to be noted however that Committee for Risk Assessment (RAC) (ECHA, 2012) stated it its opinion on the proposal for harmonised classification and labelling of formaldehyde as regards of carcinogenicity that the database for low-dose effects is limited and that the data does not allow a firm conclusion on a threshold-mode of action or the identification of threshold.

However, the opinion on Biocidal Products Committee (BPC) (ECHA, 2015) on formaldehyde, Product type 3[20] provided an acceptable exposure concentration (AEC) of 0.1 mL/m^3 (0.1 ppm). The aim is to protect the general public so that re-entry of the general public should only be allowed after completion of treatment including an appropriate waiting period. After this period, the concentration of the active substance in the building should be below the corresponding reference value (i.e. 0.1 mL/m^3).

[20] Product type 3 = Veterinary hygiene

6.9. Occupational Exposure Limit values (OELs) in Europe

In 2008, SCOEL has recommended an 8-hr time weighted average (TWA) value of 0.2 ppm (or 0.2 mg/m^3) and a 15-min short term exposure limit (STEL) of 0.4 ppm (or 0.5 mg/m^3). The Commission services requested the SCOEL to review the latest scientific literature and to reconsider the previous recommendation. In 2015, SCOEL proposed new OELs: 0.3 ppm (8-hr TWA) and 0.6 ppm (STEL) (sited by RMOA, France (2016). This proposal has been under public consultation[21]. No formal decision has been taken yet.

In addition to SCOEL OELs, several Member States have their own OELs. The SCOEL recommendation has listed the OELs used in some EU countries and also in some non-EU countries.

France has used the DNEL values similar than proposed by SCOEL in 2015 in its characterisation of risk, i.e. long term DNEL for inhalation 0.3 ppm and short-term DNEL for inhalation 0.6 ppm.

6.10. Regulatory information from United States and Canada

US EPA has recently provided requirements for the composite wood products (Formaldehyde Emission Standards for Composite Wood Products (RIN 2070-AJ44) Federal Register document on July 27, 2016)[22]. The requirements for the composite wood product producers include e.g. that, certain products must comply with emission standards:

- Hardwood plywood (made with a veneer core or a composite core) = 0.05 ppm
- Particleboard = 0.09 ppm
- MDF = 0.11 ppm
- Thin MDF = 0.13 ppm

In addition, the laminated products must comply with the hardwood plywood emission standard of 0.05 ppm, and the testing, certification, and record keeping requirements for composite wood products.

In Canada[23], the Health Canada has developed an indoor air quality guideline for formaldehyde in residences (based on proposal from 2005). The guideline sets recommended maximum formaldehyde levels for two types of exposure:

- The short-term exposure limit protects against health problems that may arise from exposure to high levels over a short time period (e.g. one hour). This type of

[21] https://circabc.europa.eu/sd/a/d44aedf4-8e61-47b4-96c6-91a6ff3139f7/2015-11-16v11%20REC-125%20Formaldehyde%20stage%2040.20.pdf

[22] https://www.epa.gov/formaldehyde/formaldehyde-emission-standards-composite-wood-products-0

[23] http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/formaldehyde/index-eng.php?_ga=1.32140349.2015822811.1479290219

exposure could occur, for example, when working with paint or varnish containing formaldehyde.

- The long-term exposure limit protects against health problems that may be caused by repeated exposure to lower levels of formaldehyde over a long period (days, weeks, months, etc.). Since formaldehyde levels change over time, with occasional peaks and valleys, long-term exposure levels are best measured by sampling indoor air over a longer period (8 hours or more).

To avoid possible eye, nose and throat irritation from short-term exposure, indoor air levels of formaldehyde should be below 123 µg/m^3 (100 ppb). This is actually lower than the formaldehyde level that has been shown to cause irritation in scientific studies. The lower value was chosen to be more protective of health, as people may differ in their sensitivity to formaldehyde.

To prevent respiratory problems from long-term exposure, i.e. over days, months or years, indoor air levels should be kept below 50 µg/m^3 (or 40 ppb). As formaldehyde levels increase above this level, the risk of having respiratory problems or allergic sensitivity also increases, especially for children.

More information on non-EU legislations is available in the report of the study on the criteria for Art. 68(2) implementation (formaldehyde was a case study)[24].

7. Justification for action on a Union-wide basis

Formaldehyde and formaldehyde releasers are used in different mixtures and articles, which are used all over the Europe among the Member States (+EEA). Any measures that restrict substances as such or in mixtures or in articles need to be harmonised within the EU. ECHA has not received any such information that formaldehyde that is e.g. released from articles could be only a problem in one (or only some) Member State.

8. Assumptions, uncertainties and sensitivities

For this report, information from substance evaluation on formaldehyde by France and the Netherlands, scientific literature, registration dossiers and from the stakeholders as received during the call for evidence has been used. ECHA was not able to analyse in detail all the statements in the scientific articles or in the received comments, as this would have required a more in-depth literature review. In case the Commission requests ECHA to prepare an Annex XV restriction proposal, more detailed analysis will be carried out.

9. Stakeholder consultation

ECHA launched a call for evidence on the use of formaldehyde releasers on their own, in mixtures or in articles, by workers, professionals and consumers on 13 July 2016, which ended on 14 October 2016. 36 comments were received during the call. In addition, ECHA contacted separately some stakeholders and received information by others outside the call. The summaries of the comments are in Annex 3.

[24] http://ec.europa.eu/DocsRoom/documents/13035/attachments/1/translations

ECHA notes, that during the call for evidence ECHA received information, that some substances that release formaldehyde are used as biocides even though they are not listed under the review programme under Biocidal Product Regulation.

10. Conclusions

10.1. Formaldehyde

Based on the information in the draft RMOA prepared by France there appears to be a risk to workers from one or more uses of formaldehyde. In relation to consumer, there are many more uncertainties related to the exposure and the health based limit value to be used. Information on exposure may become available from the Substance Evaluation in late 2017. However, there seem to be divergent views what can be regarded as a protective limit value of formaldehyde in indoor air, even though the one proposed by WHO is supported by other scientific studies. However, peak concentrations may need to be taken into account if a limit value is developed.

10.2. Formaldehyde releasers (or possible formaldehyde releasers)

Substances identified in this investigation

Known formaldehyde releasers are described in Tables 6 (intentional releases under Biocidal and Cosmetic Product Regulations) and 7 (known releasers) in Annex 2. ECHA has received many registration dossiers, which have formaldehyde as a composition or as an impurity (Table 7 in Annex 2). Whether all these release formaldehyde or not is not known.

Comments received during the call for evidence emphasised to distinct the intentional and non-intentional release of formaldehyde, thus ECHA has categorised the substances as described in the report. Some substances identified in the scientific literature have different mode of action and they are not releasing formaldehyde.

Uses of formaldehyde releasers and possible formaldehyde releasers

The registration data provides information on uses of formaldehyde releasers and potential formaldehyde releasers; however, the information is often rather general. Therefore, in Tables 7 and 9 in Annex 2, the uses cover also their possible use as biocide under the Biocidal Product Regulation and as preservatives as listed in Annex V to Cosmetic Product Regulation. These uses are outside the scope of this report otherwise.

Other uses (than biocidal/preservative uses) where formaldehyde could be released are the uses of the substances as such, e.g. as corrosion inhibitor, solvent in certain photochemicals, textile finishing products, binding agent in paints, lacquers, adhesives. However, formaldehyde may be released also from articles – such as building and insulating materials, wood-based panels, textiles etc. when formaldehyde releasers are used in the production. Information on uses gathered so far is described in this investigation report; however, more information on substance specific uses would be desirable.

General conclusions on emissions and exposure including safety limits

Formaldehyde emissions to indoor air has been decreased due to regulatory and voluntary actions (especially for construction materials) being around 20-40 µg/m^3 under normal living conditions (Salthammer T. et al. (2010)). Authors of this review report however noted

that these average concentrations do not take into account the higher exposure which may result from new buildings or special indoor conditions, peak concentrations, and individual cases. A test chamber study by Salthammer T. and Mentese S. from 2008 showed that it was not possible to achieve concentrations lower than 20 µg/m^3 even with low-emitting materials. When the test chamber was equipped with carpet, carpet adhesive and a side board made of lacquered particle board the concentration of formaldehyde increased.

These uses of formaldehyde releasers are likely to contribute to worker and consumer exposure and a number of such releasers (and potential releasers) have been identified as being within the scope of REACH. This issue needs further examination as to its contribution to expected exposures to formaldehyde.

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Annex 1 - Information required by ECHA due to substance evaluation

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) of formaldehyde (Registrant(s))

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 µg/m2/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 panelling 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).

Annex 2 - Tables with formaldehyde releasers or potential formaldehyde releasers

Table 5. FORMALDEHYDE RELEASERS USED AS BIOCIDES AND IN COSMETICS

Entry numbers in the Biocide Review Programme Regulation	Substance	CAS No	Product type (PT)[25]	Rapporteur Member State
359	(ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	3586-55-8	2, 6, 11, 12 and 13	Poland
368	Methenamine 3-chloroallylochloride (CTAC)**	4080-31-3	6, 12 and 13	Poland
377	2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)	4719-04-4	6, 11, 12 and 13	Poland
393	1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH)* and ***	6440-58-0	6 and 13	Poland
797	cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	51229-78-8	6 and 13	Poland
444	7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)***	7747-35-5	6 and 13	Poland
531	(benzyloxy)methanol	14548-60-8	6 and 13	United Kingdom
566	.alpha.,.alpha.',.alpha.''-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (HPT)	25254-50-6	2, 6, 11 and 13	Austria
656	3,3'-methylenebis[5-methyloxazolidine] (Oxazolidin / MBO)	66204-44-2	2, 6, 11, 12 and 13	Austria
387	N,N'-methylenebismorpholine (MBM)	5625-90-1	6 and 13	Austria
691	Sodium N-(hydroxymethyl)glycinate*	70161-44-3	6	Austria
382	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)	5395-50-6	2, 6, 11, 12 and 13	Spain
N/A	2-Bromo-2-nitropropane-1,3-diol	52-51-7		

[25] PT2=Disinfectants and algaecides not intended for direct application to humans or animals, PT6=Preservatives for products during storage, PT11=Preservatives for liquid-cooling and processing systems, PT12=Slimicides and PT13=Working or cutting fluid preservatives.

	(INCI)) ** and ***			
N/A	Diazolidinyl urea (INCI) * and ***	78491-02-8		
N/A	Formaldehyde (INCI, MI) * and ***	50-00-0		
N/A	Imidazolidinyl urea (INCI, MI) * and ***	39236-46-9		
N/A	Methenamine (INCI, MI) **and ***	100-97-0		
N/A	Paraformaldehyde*	30525-89-4		
N/A	5-Bromo-5-nitro-1,3-dioxane (INCI)**	30007-47-7		

* Substances included in Annex V of the Cosmetic Product Regulation (EC No 1223/2009) and in the opinion of The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (The determination of certain formaldehyde releasers in cosmetic products, 2002): http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out188_en.pdf

** Substances included in Annex V of the Cosmetic Product Regulation but not in the "The determination of certain formaldehyde releasers in cosmetic products, 2002"

*** Registration dossier submitted to ECHA

Table 6. LIST OF SUBSTANCES IDENTIFIED AS FORMALDEHYDE RELEASERS BY OTHER SOURCES			
Commonly used name	**IUPAC name**	**Other synonyms**	**CAS number**
Trade name**	4,4-Dimethyloxazolidine ; 3,4,4-trimethyloxazolidine		81099-36-7 (ingred. 75673-43-7 and 51200-87-4)
Trade name**	4-[2-(Morpholin-4-ylmethyl)-2-nitro-butyl]morpholine; 4-(2-nitrobutyl) morpholine	Mixture of nitrobutylmorpholine and ethylnitrotrimethylenedi morpholine	37304-88-4 (ingred. 1854-23-5 and 2224-44-4)
Dihydroxydimethyloletheleneurea, methylated	4,5-Dihydroxy-1,3-bis(hydroxymethyl)-imidazolidin-2- one, methylated	Dimethylolglyoxalurea, methylated	68411-81-4
Dimethylhydantoin formaldehyde resin	5,5-Dimethylimidazolidine-2, 4-dione, formaldehyde	Formaldehyde, polymer with 5,5-dimethyl-2,4-imidazolidinedione; DMHF	26811-08-5
Dimethyloldihydroxyethyleneurea	4,5-Dihydroxy-1,3-bis (hydroxymethyl)-imidazolidin-2- one	1,3-Bis(hydroxymethyl)-4,5-dihydroxy-2-imidazolidinone	1854-26-8
Dimethylolethyleneurea	1,3-Bis(hydroxymethyl) imidazolidin-2-one		136-84-5
Dimethylolpropyleneurea	1,3-Bis(hydroxymethyl) -1,3-diazinan-2-one	DMPU; Tetrahydro-1,3-bis(hydroxymethyl)-1H- pyrimidin-2-one	3270-74-4
Dimethylol urea (INCI)	1,3-Bis(hydroxymethyl) urea	*N,N′*-Bis(hydroxymethyl)urea; Carbamol;	140-95-4

		Dihydroxymethylurea; *N,N'*-dimethylolurea; Dimethylurea; Oxymethurea (MI); Urea formaldehyde	
Trade name**	(Z)-3-(Bis(2-hydroxyethyl)amino)-2- (2-hydroxyethyl-(hydroxymethyl)amino) prop-2-en-1-ol	2-Hydroxymethylamino- ethanol-tri-*N*-ethylhydroxy-2-amino-methylene	77044-78-1
Trade name**	1,3,5-Triethyl-1,3,5-triazinane (b)	(b) Hexahydro-1,3,5-triethyl-s-triazine; (b) Triethyl-trimethylenetriamine mixture of (a) triazinetriethanol (see there) and (b) hexahydro-1,3,5-triethyl-1,3,5- triazine	7779-27-3 (b)
Glyoxalurea	4,5-Dihydroxyimidazolidin-2-one	Dihydroxyethyleneurea; Glyoxalmonoureine	3720-97-6
MDM hydantoin (INCI)	1-(Hydroxymethyl)-5,5-dimethyl-imi-dazolidine-2,4-dione	1-Hydroxymethyl-5,5-dimethyl hydantoin (MI); MDMH; Methylol dimethyl hydantoin; Monomethylol dimethyl hydantoin	116-25-6

N-Methylol-chloracetamide	2-Chloro-N -(hydroxymethyl) acetamide	Chloroacetamide-N -methylol	2832-19-1
Methylol urea	Hydroxymethylurea	*N*-(hydroxymethyl)urea; Methyl hydroxyurea; Mono(hydroxymethyl)urea; Monomethylolurea;	1000-82-4
Paraformaldehyde	Formaldehyde	Paraform; Poly(oxymethylene)	30525-89-4
Polyoxymethylene melamine (INCI)	Not available	Melamine, polymer with formaldehyde; Melamine/formaldehyde resin; Nanoplast	9003-08-1
Polyoxymethylene urea (INCI)	Formaldehyde; urea	Polynoxylin; Urea–formaldehyde resin; Urea, polymer with formaldehyde	9011-05-6
Formaldehyde dibenzyl acetal			2749-70-4
Propyleneglycol hemiformal	Not available		
Tris(hydroxymethyl)-nitromethane (INCI, MI)	2-(Hydroxymethyl)-2-nitropropane- 1,3-diol	Nitromethylidynemethanol; Trimethylolnitromethane; Tris nitro	126-11-4

Hydantoin	Imidazolidine-2,4-dione	Glycolylurea; 2-Hydroxy-2-imidazolin-4 (or 5)-one	461-72-3
(Hydroxymethyl)-5,5-dimethyl-2-4-imidazolidinedione	Not available		27636-82-4
3-(Hydroxymethyl)-5,5-dimethylimidazolidine-2,4- dione	As in column 1	4,4-Dimethyl-2,5-dioxo-1-imidazolidenemethanol	16228-00-5
Methylal (INCI, MI)*	Dimethoxymethane	2,4-dioxapentane; Formal; Formaldehyde dimethyl acetal	109-87-5
N-Methylolethanolamine	2-(Hydroxymethylamino)ethanol		34375-28-5

* Registration dossier submitted to ECHA

** Trade name is mentioned in de Groot A.C. et al. (2009) (see reference above)

Table 7. REGISTERED SUBSTANCES WITH FORMALDEHYDE (FA) IN THEIR COMPOSITION AND INFORMATION ON USES PROVIDED IN REGISTRATION DOSSIERS						
REGISTERED SUBSTANCES CONTAINING FA IN THEIR COMPOSITION				INFORMATION ON USES IN REGISTRATION DOSSIERS		
EC no	Substance Name	FA present as	Conc. range of FA	Use at industrial sites	Use by professional workers	Use by consumers
200-580-7	acetic acid	impurity	≤0.006 % (w/w)	cleaning agents, oil field drilling and production, waste water treatment chemicals, intermediate, laboratory reagents, fuel, intermediates.	water treatment chemicals, cleaning agents, laboratory use	agrochemical uses, cleaning agents, pH adjustment of textile dyes
200-879-2	methyloxirane	impurity	ca.2.75E-4 % (w/w)	intermediate, use in polymer production	laboratory use	lubricants, functional fluids, de-icing, coatings, agrochemical
203-471-2	prop-2-yn-1-ol	impurity	≥0.0 ≤0.2 % (w/w)	coatings, cleaning agents, functional fluids, (corrosion inhibitor) intermediate, laboratory reagent	coatings, cleaning agents, functional fluids (corrosion inhibitor), laboratory reagent	
203-612-8	hexahydro-1,3,5-trimethyl-1,3,5-triazine	impurity	≥0.0 <0.1 % (w/w)	Used as H2S scavenger in oil and gas production systems.	fuel preparation (professional)	

203-640-0	4-methylmorpholine	impurity	≥0.0 <0.2 % (w/w)	auxiliary for polymerisation, use in lab, industrial production and use of rigid polyurethane foam	Use in Polymerisation reactions as monomer or auxiliary (e.g. plastic, resins, rubber, epoxy-systems), laboratory reagents, professional use of coatings, adhesives, sealants and elastomers, professional production and use of rigid polyurethane form.	
203-788-6	but-2-yne-1,4-diol	impurity	<0.02 % (w/w)	coatings, electroplating, cleaning/brightening, surface application, intermediate, use in functional fluids.	use in laboratories, functional fluids (professional)	
203-812-5	1,3,5-trioxane	impurity	≥0.0 <0.002 % (w/w)	monomer,	laboratory reagent	
203-920-2	bis(2-chloroethoxy)methane	impurity	≥0.0 <0.1 % (w/w)	monomer		
204-327-1	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	impurity	≥0.0 <0.02 % (w/w)	hydraulic fluids, lubricants, rubber and non-rubber polymers, adhesives, sealants, fuels, laboratory reagent.	laboratory reagent, hydraulic fluids, lubricants, metalworking fluids	
207-330-6	diethoxymethane	impurity	≥0.0 ≤0.01 % (w/w)	solvent, intermediate, coating	laboratory reagent, cleaning, coating	coating, cleaning products
209-141-4	3-methylbut-2-en-1-ol	impurity	≥0.3 <1.0 % (w/w)	fuels		

211-463-5	1,3-dioxolane	impurity	≥0.0 <0.1 % (w/w)	monomer, lubricants, intermediate , binder , coatings, metal working fluids, laboratory reagent	use in laboratories, de-icing, polymer processing, binder and release agent, coating	
213-086-1	N-(hydroxymethyl)methacrylamide	impurity	≥0.0 <2.0 % (w/w)	monomer		
213-103-2	N-(hydroxymethyl)acrylamide	impurity	≥0.0 <0.06 % (w/w)	monomer		
219-909-0	1,1'-[methylenebis(oxy)]dibutane	impurity	<0.05 % (w/w)	cleaning agents, fragrances, rubber production	polymer processing, fragrances and cleaning products, labs, polishes and wax blends, agrochemistry	agrochemistry, fragrances.
224-631-8	2,5,7,10-tetraoxaundecane	impurity	≥0.0 <0.1 % (w/w)	intermediate , coatings, rubber production	Agrochemicals , coating	
229-146-5	nitrilotrimethylenetris(phosphonic acid)	impurity	>0.0 <0.05 % (w/w)	cleaning agents, pains/coatings, anti-scalant, metal surface treatment, textile bleaching,	cleaning products, paints/coatings, agriculture, personal care products, cement retardation	paints/coatings, cleaning products, agrochemicals, personal care products,
231-915-5	potassium sulfate	impurity	≥0.0 ≤0.05 % (w/w)	treatment of articles, textile/leather/ paper industry, use in dyes, fertilisers, intermediate , cosmetics, manufacture of catalysts	cleaning agents, fertilisers, plant protection products, treatment of articles, construction materials, laboratory chemicals	fertilisers, plant protection products, construction materials, de-icing products
243-528-9	dimethyl [3-[(hydroxymethyl)amino]-3-oxopropyl]phosphonate	impurity	>0.0 <2.5 % (w/w)	Flame retardant used in textile finishing		Service-life: use of technical textiles with flame resistant properties.
244-815-1	3,3'-[methylenebis(oxymethylene)]bisheptane	impurity	≤0.01 % (w/w)	coatings	cleaning products	

274-986-8	Formaldehyde, reaction products with m-phenylenediamine, sodium sulfide (Na2S) and sulfur	impurity	>0.0 ≤0.01 % (w/w)	textiles		
296-664-6	Urea, reaction products with formaldehyde and glyoxal	constituent	>0.05 <1.5 % (w/w)	textile applications		
296-665-1	Urea, reaction products with formaldehyde, glyoxal and methanol	constituent	≥0.0 ≤0.1 % (w/w)	textile applications		
401-230-8*	A mixture of: 2-[N-(2-hydroxyethyl)stearamido] ethyl stearate; sodium [bis[2-(stearoyloxy)ethyl]amino]methylsulfonate; sodium [bis(2-hydroxyethyl)amino]methylsulfonate; N,N-bis(2-hydroxyethyl)stearamide	impurity	0.01 % (w/w)			
401-280-0	1-(N,N-bis(2-ethylhexyl)aminomethyl)-1,2,4-triazole	impurity	≤1%	lubricants, metal working fluids (metal deactivator for protecting of copper and its alloys from sulphur)		
401-530-9*	Reaction product of: (2-hydroxy-4-(3-propenoxy)benzophenone and triethoxysilane) with (hydrolysis product of silica and	impurity	0.01 % (w/w)			

	methyltrimethoxysilane)					
402-360-8*	disodium N-carboxymethyl-N-(2-(2-hydroxyethoxy)ethyl)glycinate	impurity	0.07% (w/w)			
404-160-6*	Reaction products of: 4-nonylphenol, formaldehyde and dodecane-1-thiol	impurity	≥0.0 <0.1 % (w/w)			
410-460-8*	Weichmacher Tamol	impurity	0.03% (w/w)			
412-350-5	2-methyl-1,3-propanediol	impurity	≥0.0 ≤0.05 % (w/w)	coatings, cleaning agents, binders, polymer production, solvent	agriculture, laboratory, solvent in inks, de-icing, cleaning agents	de-icing, solvent, cleaning products
412-380-9	2,2-dibromo-2-nitroethanol	impurity	≥1.5 ≤ 2.3 % (w/w)	used as biocide in water cooling systems		
412-790-8*	A mixture of: N-[3-hydroxy-2-(2-methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide; N-[2,3-bis-(2-methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide; methacrylamide; 2-methyl-N-(2-methylacryloylaminomethoxymethyl)acrylamide; N-(2,3-dihydroxypro	impurity	0.01 % (w/w)			

	poxymethyl)-2-methylacrylamide					
414-070-9*	trisodium N,N-bis(carboxymethyl)-β-alanine	impurity	<20 ppm			
414-350-0*	Ucar Polyphobe Thickener (stripped)	impurity	≥0.0 ≤0.01 % (w/w)			
416-470-9*	N-[(benzotriazole-1-yl)methyl)]-4-carboxybenzenesulfonamide	impurity	≥0.08 ≤0.09 % (w/w)			
417-540-1	A mixture of: tetrasodium(((2-hydroxyethyl)imino)bis(methylene))bisphosphonate, N-oxide; trisodium ((tetrahydro-2-hydroxy-4H-1,4,2-oxazaphosphorin-4-yl)methyl)phosphonate, N-oxide, P-oxide	impurity	>0.0 <0.2 % (w/w)	corrosion inhibitors		
420-760-0*	Ucar Polyphobe Thickener N	impurity	≥0.0 ≤0.01 % (w/w)			

422-720-8*	UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine	impurity	≥0.0 ≤1.4 % (w/w)	flame retardant		
423-230-7*	4,4'-(oxy-(bismethylene))-bis-1,3-dioxolane	impurity	≥0.0 ≤0.05 % (w/w)	intermediate		
427-280-0*	poly-[((4-((4-ethyl-ethylene)amino)phenyl)-((4-(ethyl-(2-oxyethylene)amino)phenyl)methinyl)cyclohexa-2,5-dienylidene)-N-ethyl-N-(2-hydroxyethyl)ammonium acetate]	impurity	<0.001%			
427-480-8*	poly-[((4-((4-(ethyl-ethylene)amino)phenyl)-(4-(ethyl-(2-oxyethylene)amino)phenyl)methinyl)-3-methylcyclohexa-2,5-dienylidene)-N-ethyl-N-(2-hydroxyethyl)ammonium acetate]	impurity	1.0E-4 0.01 % (w/w)			
428-170-5*	XB 3123 ES	impurity	≥0.0 ≤0.15 % (w/w)			
429-340-1	N-methyl-N-cyanomethyl morpholiniummethylsulfate	impurity	≥0.006 ≤0.025 % (w/w)	process regulators		
430-580-4*	2,2-dialkyl-4-hydroxymethyl-1,3-dioxolane	impurity	≥0.0 ≤0.001 % (w/w)			
431-060-1	N-nitro-N-(3-methyl-3,6-dihydro-2H-1,3,5-oxadiazin-4-yl)amine	impurity	≥0.0≤ 0.2 % (w/w)	intermediate		

431-200-1*	4-(cyanomethyl)-4-methylmorpholin-4-ium hydrogen sulfate	impurity	5.0E-4 0.005 % (w/w)			
432-220-1*	TRITON SP-140 SURFACTANT	impurity	≥0.0 ≤0.001 % (w/w)			
432-440-8*	reaction products of diisopropanolamine with formaldehyde (1:4)	impurity	≥0.0 <2.0 % (w/w)			
435-960-3	diethyl (2-(hydroxymethylcarbamoyl)ethyl)phosphonate	impurity	≥1.5 ≤4.0 % (w/w)			
436-230-7	Phosphonium, tetrakis(hydroxymethyl)-, chloride (1:1), reaction products with 1-tetradecanamine and urea (Monomer)	impurity	≥0.0 ≤0.99 % (w/w)	flame retardant		
450-000-3*	name confidential or not available	impurity	1.0E-4 % (w/w)			
456-340-9*	name confidential or not available	impurity	≥0.0 <.0.002 % (w/w)			
500-057-6	Tetrakis(hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea	impurity	≥0.0 ≤0.09 % (w/w)	intermediate, coatings, rubber production		
692-061-0	Fast Pyrolysis Bio-oil	constituent	≥0.0 <0.5 % (w/w)	fuel		
911-694-8	Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol	impurity	≤0.02 % (w/w)		laboratory reagent	

911-811-2	Reaction mass of [[(2-hydroxyethyl)imino]bis(methylene)]bisphosphonic acid and Phosphonic acid, P-[(tetrahydro-2-hydroxy-2-oxido-4H-1,4,2-oxazaphosphorin-4-yl)methyl]-	impurity	ca.0.02 % (w/w)	scale inhibition, bleaching agent, metal surface treatment		
938-828-8	Iron(III) chloride, complex with reaction products of 2,2'-(ethane-1,2-diyldiimino)diacetic acid, formaldehyde, phenol and potassium hydroxide	constituent	<0.1 % (w/w)	production of mixtures for use in agriculture	use of chelates in agriculture	use of chelates in agriculture
939-056-4	Reaction product of urea, formaldehyde, glyoxal and diethylene glycol	constituent	≥0.2 ≤0.4 % (w/w)	textile application		
939-460-0	Reaction product of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and phenol, heptyl derivs.	impurity	<0.1 % (w/w)	lubricants	lubricants	lubricants
939-513-8	Reaction mass of [[(2-hydroxyethyl)imino]dimethylene]bisphosphonic acid, sodium salt and 4-(Phosphonomethyl)-2-hydroxy-2-oxo-1,4,2-oxazaphosphorinane, sodium salt	impurity	≤0.02 % (w/w)	scale inhibitor, bleaching agent	personal care products	personal care products
* Notificaton of New Substances (NONs) included in the European List of Notified Chemical Substances (ELINCS). No information on use is available.						

Table 8. FORMALDEHYDE RELEASERS REGISTERED, NUMBER OF REGISTRATIONS AND TONNAGE RANGE REGISTERED (SEARCH MADE ON 18 JAN 2017)

Substance name	CAS number	EC Number	Number of registrants	Tonnage range (manufactured or imported per annum)
7a-ethyldihydro-1H,3H,5H-oxazolo[3,4-c]oxazole	7747-35-5	231-810-4	1 registration, 1 joint submission	Full registration (100 – 1 000 tonnes per annum)
1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea	78491-02-8	278-928-2	2 registrations, 1 joint submission	Full registration (100-1 000 tonnes per annum)
1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	6440-58-0	229-222-8	2 registrations, 1 joint submission	Full registration (100-1 000 tonnes per annum)
N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]	39236-46-9	254-372-6	2 registrations, 1 joint submission	Full registration (100-1 000 tonnes per annum)
methenamine	100-97-0	202-905-8	8 registrations, 1 joint submission	Full (joint) registration (10 000 - 100 000 tonnes per annum)
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	4719-04-4	225-208-0	8 registrations, 1 joint submission	Full registration (10 000-100 000 tonnes per annum)
dimethoxymethane	109-87-5	203-714-2	2 registrations, 1 joint subm.	Full registration (1 000 - 10 000 tonnes per annum)

Table 9. INFORMATION ON USES OF FORMALDEHYDE RELEASERS FROM THE REGISTRATION DOSSIERS, FROM DK PRODUCT REGISTER DATABASE (FROM 2009), FROM STAKEHOLDERS ETC.

CAS Nr	Name	Information in registration dossiers					Uses according to Danish product register database	Other source of information
		Sub. Registered?	Manuf. in EU	Ind. use	Prof. use	Cons. use		
7747-35-5*	EDHO	Yes	No	Formulation for use in leather tanning			Cooling agent for metal processing	
78491-02-8*	Diazolidinyl urea (INCI)	Yes	Yes	Formulation		Consumer use not specified (processing aid)	-	
6440-58-0*	DMDMH	Yes	Yes	Use in manufacture of cosmetic products		Cosmetics	-	
39236-46-9*	Imidazolidinyl urea (INCI, MI)	Yes	Yes	Formulation		Consumer use not better specified (processing aids)	-	
100-97-0*	Methenamine (INCI, MI)	Yes	Yes	Production of polymers and rubber (curing agent). Use as intermediate in production	Professional use (not specified)	Consumer use (not specified)	Adhesives Biocides - pesticides for non-agricultural uses Cleaning/washing agents Metal surface treatment remedies Paint, lacquers and	Substance for which KEMI (Sweden) has suggested a limit value in construction products. Used in tyres to improve adhesion of rubber to brass coated

				of explosives			varnishes Rust inhibitors	steel cord or textile and hoses or belts to improve adhesion of rubber to textile. Used as Transported Isolated Intermediate in chemical synthesis of resins and other substances. Used as curing agent in phenolic and epoxy resins. Also used in production of explosives.
4719-04-4*	HHT	Yes	Yes	Formulation for use in oilfield and treatment of hydrocarbons			Biocides - pesticides for non-agricultural uses Cleaning/washing agents Cooling agents for metal processing Lubricants Paint, lacquers and varnishes Printing inks Rust inhibitors	Scavanger for sulphide in refinery and/or oilfield application. (No free formaldehyde is being formed during this reaction.)
109-87-5**	Methylal (INCI, MI)	Yes	Yes	Formulation for use as processing aid and intermediate.	Professional use as processing aid and inclusion into matrix. Professional use of long life articles with high release (abrasive processing)	Consumer use as processing aid. Inclusion into matrix. Consumer use of long life articles with high release (abrasive processing)	-	Used in chemical synthesis (e.g. in the synthesis of cyclic compounds or dimers). Used in the manufacturer of chemicals.
68002-20-0	Hexa(methoxymethyl)melamine	No						Used in tyres to improve adhesion of rubber to brass coated steel cord or textile and

								hoses or belts to improve adhesion of rubber to textile. (Cannot fully replace HMT in all applications)
2682-20-4	Methylisothiazolinone	No						Substance for which KEMI (Sweden) has suggested a limit value in construction products.
26172-55-4	5-Chloro-2-methyl-3(2H)-isothiazolone	No						Substance for which KEMI (Sweden) has suggested a limit value in construction products.
30525-89-4	Paraformaldehyde	No						A source of monomer in condensation polymerisation of aminoplast resins. Use as raw material in chemical reaction at industrial plants.
461-72-3	Imidazolidine-2,4-dione	No						Used as a research and development bonging agent.
9011-05-6	Urea formaldehyde (UF) resins	No						Used as cross linkers in production of thermosettings adhesives further used in production of particle boards, plywood and MDS.
9003-08-1	Melamine formaldehyde (MF) resins	No						Used for wood adhesives and high end applications like laminates, surface coating for cars.
30525-	Paraformaldehyde	No						Used as transported

89-4								isolated intermediate in chemical synthesis of resins and other substances.

* formaldehyde is not present in the substance (as constituent and/or as impurity)

** formaldehyde is present in the substance as impurity with typical composition of 0.005%

Table 10. FORMALDEHYDE RELEASERS FOR WHICH THE COMMITTEE FOR RISK ASSESSMENT HAS ADOPTED OPINIONS ON HARMONISED CLASSIFICATION	
Name of the substance	**Reference**
4,4'-methylenedimorpholine [MBM]	http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12647/term
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); [MBO]	http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12646/ter.m
Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1); [HPT]	http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12645/term

Note: a proposal for a harmonised classification for Sodium N-(hydroxymethyl)glycinate is under evaluation by RAC.

Table 11. IDENTIFIED FA RELEASERS AND REGISTERED SUBSTANCES WITH FA IN THEIR COMPOSITION WITH HARMONISED CLASSIFICATION

EC number	NAME	CATEGORY	STATEMENT
202-905-8*	methenamine	Flam. Sol. 2 Skin Sens. 1	H228 H317
225-208-0*	2,2',2"-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	Acute Tox. 4 Skin Sens. 1	H302 H317
200-580-7**	acetic acid … %	Flam. Liq. 3 Skin Corr. 1A	H226 H314
200-879-2**	propylene oxide	Flam. Liq. 1 Carc. 1B Muta. 1B Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	H224 H350 H340 H332 H312 H302 H319 H335 H315
203-471-2**	prop-2-yn-1-ol	Flam. Liq. 3 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Aquatic Chronic 2	H226 H331 H311 H301 H314 H411
203-788-6**	but-2-yne-1,4-diol	Skin Corr. 1B Acute Tox. 3 Acute Tox. 3 Acute Tox. 4 STOT RE 2 Skin Sens. 1	H314 H331 H301 H312 H373 H317
203-812-5**	1,3,5-trioxan	Flam. Sol. 1 Repr. 2 STOT SE 3	H228 H361d H335
211-463-5**	1,3-dioxolane	Flam. Liq. 2	H225
401-230-8**	N,N-bis(2-hydroxyethyl)stearamide	Aquatic Chronic 3	H412
401-280-0**	N,N-bis(2-ethylhexyl)-((1,2,4-triazol-1-yl)methyl)amine	Skin Corr. 1B Skin Sens. 1 Aquatic Chronic 2	H314 H317 H411
401-530-9**	reaction product of: (2-hydroxy-4-(3-propenoxy)benzophenone and triethoxysilane) with (hydrolysis product of silica and methyltrimethoxysilane)	Flam. Sol. 1 STOT SE 1 Acute Tox. 4 Acute Tox. 4 Acute Tox. 4	H228 H370 H332 H312 H302
402-360-8**	disodium N-carboxymethyl-N-(2-(2-hydroxyethoxy)ethyl)glycinate	Eye Dam. 1	H318
404-160-6**	4-nonylphenol, reaction products with formaldehyde and dodecane-1-thiol	Skin Sens. 1 Aquatic Chronic 4	H317 H413

412-380-9**	2,2-dibromo-2-nitroethanol	Expl. 1.1 Carc. 2 Acute Tox. 4 STOT RE 2 Skin Corr. 1A Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H201 H351 H302 H373 H314 H317 H400 H410
412-790-8**	N-[2,3-bis-(2-methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide	Carc. 1B Muta. 2 STOT RE 2	H350 H341 H373
414-070-9**	trisodium N,N-bis(carboxymethyl)-β-alanine	Skin Corr. 1B Aquatic Chronic 3	H314 H412
416-470-9**	N-[(benzotriazole-1-yl)methyl)]-4-carboxybenzenesulfonamide	Eye Irrit. 2 Aquatic Chronic 2	H319 H411
417-540-1**	trisodium ((tetrahydro-2-hydroxy-4H-1,4,2-oxazaphosphorin-4-yl)-methyl)phosphonate, N-oxide, P-oxide	Eye Dam. 1 Aquatic Chronic 2	H318 H411
422-720-8**	UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine	Carc. 2 Acute Tox. 4 STOT RE 2 Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H373 H314 H317 H400 H410
423-230-7**	4,4'-(oxy-(bismethylene))-bis-1,3-dioxolane	Eye Dam. 1	H318
424-210-0**	2,2''-dihydroxy-4,4''-(2-hydroxy-propane-1,3-diyldioxy)dibenzophenone	Aquatic Chronic 4	H413
427-280-0**	poly-[((4-((4-ethyl-ethylene)amino)phenyl)-((4-(ethyl-(2-oxyethylene)amino)phenyl)methinyl)cyclohexa-2,5-dienylidene)-N-ethyl-N-(2-hydroxyethyl)ammonium acetate]	STOT SE 3 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H335 H315 H318 H400 H410
427-480-8**	poly-[((4-((4-(ethyl-ethylene)amino)phenyl)-(4-(ethyl-(2-oxyethylene)amino)phenyl)methinyl)-3-methylcyclohexa-2,5-dienylidene)-N-ethyl-N-(2-hydroxyethyl)ammonium acetate]	STOT SE 3 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H335 H315 H318 H400 H410
429-340-1**	N-methyl-N-cyanomethylmorpholiniummethylsulfate	Acute Tox. 4 Eye Dam. 1	H302 H318
429-460-4**	2,6-bis(1,1-dimethylethyl)-4-(phenylenemethylene)cyclohexa-2,5-dien-1-one	Skin Sens. 1 Aquatic Chronic 4	H317 H413
430-580-4**	2,2-dialkyl-4-hydroxymethyl-1,3-dioxolane	Skin Irrit. 2 Aquatic Chronic 2	H315 H411
431-060-1**	N-nitro-N-(3-methyl-3,6-dihydro-2H-1,3,5-oxadiazin-4-yl)amine	Acute Tox. 4 Skin Sens. 1 Aquatic Chronic 3	H302 H317 H412
431-200-1**	4-(cyanomethyl)-4-methylmorpholin-4-ium hydrogen sulfate	Acute Tox. 4 Eye Dam. 1 Skin Sens. 1	H302 H318 H317

431-490-8**	4-(3-triethoxysilylpropoxy)-2-hydroxybenzophenone	Aquatic Chronic 2	H411
432-440-8**	reaction products of diisopropanolamine with formaldehyde (1:4)	Carc. 2 Acute Tox. 4 Skin Corr. 1B Skin Sens. 1 Aquatic Chronic 2	H351 H302 H314 H317 H411
435-960-3**	methyl ethyl (2-(hydroxymethylcarbamoyl)ethyl)phosphonate	Carc. 1B Muta. 1B Skin Sens. 1	H350 H340 H317
* Identified FA releasers (included in Table 6) ** substances with FA in their composition (included in Table 7)			

Annex 3 - Stakeholder information

Summary table of comments from the Call for Evidence and direct contacts by the stakeholders - Formaldehyde releasers

Call for evidence from 13/07/2016 to 04/10/2016: Related link- ECHA

Specific information requests:

1. Do you hold relevant information on the current uses of the formaldehyde releasers identified in the tables in the background note? If so, please provide information of the typical applications (e.g. as a mixture used for [provide details of the use], use in specific materials [details of the materials] which are used in production of articles [details of the articles]. Provide information on the function (e.g. hardener, viscosity modifier etc.) of the substance in the mixture and article as well.

2. Please provide us information on additional substances that are formaldehyde releasers, other than those listed in the tables of the background note, including their names, and if possible their EC and CAS numbers. In case you have information requested in the first question concerning these substances, please provide this information here as well.

3. Do you hold relevant information on tonnages/range of tonnages (per year) manufactured, imported and used of any formaldehyde releasers in the EU. Please provide this information here.

4. Do you hold information on imports of articles (e.g. type of article, quantity imported per year), where formaldehyde releasers are used? Please provide this information here.

5. In case you have relevant information on emissions and exposure (to workers and/or consumers) of formaldehyde from the use of formaldehyde releasers, we would appreciate to receive this information here (references to the published studies or if studies are not published – information can be provided here).

Comments received directly from the call for evidence	
Submitter/Country	**Summary of the comment**
Individual/Germany	**Information on substance and uses** Quaternium-15 (CTAC) is listed in Annex V of the Cosmetics Regulation as preservative with permitted concentration of 0.2%. Cis and trans isomers are not considered safe by SCCS (Scientific Committee on Consumer Safety of the EC). CTAC is known to be a formaldehyde (FA) releaser. FA is a degradation product of CTAC. **General discussion on releases and exposure** Most FA donors contain FA bound as methylol groups (-CH2-OH). Release speed of FA from donors depend on chemical structure and other factors (e.g. pH). The study analysied the release of FA from O-formal compounds (such as benylheminformal) and amine based-N-formal and amide-based-N-formal compounds. The study demonstrates that only amide-based-N formals are a reservoir of FA (slow FA releasers) , while O-formals and amine-based-N-formals (such as hydroxymethylglycinate) decompose completely (fast FA releasers). The study investigated the evaporation of FA from various cosmetic products during use in small bathroom. Investigated only products contained slow (and amid-based) FA releasers. The study concluded that concentrations of FA evaporated from cosmetics are considered safe under the conditions of the study.
Company/United Kingdom	**Informationon substance and uses** Paraformaldehyde as monomer in condensation polymerisation of aminoplast resins Paraformaldehyde is used in production of aminoplast resins. **General discussion on releases and exposure** Workers potentially exposed in production plants of aminoplast resins. Local Exhaust Ventilation , containment and abatement systems are used to minimise emissions and control exposure.
Company/Germany	**Informationon substance and uses** a. Bronopol: 2-bromo-2-nitropropane-1,3-diol; CAS No.: 52-51-7 b. Bronidox: 5-bromo-5-nitro-1,3-dioxane; CAS No.: 30007-47-7 *Bronopol* is listed in Biocidal Product Regulation (BPR) as supported substance for disinfectants and algaecides not intended for direct application to humans and animals and as preservative for produts during storage, preservative for liquid cooling and processing systems, and slimicide. Bronopol is an approved preservative under Cosmetic Product Regulation (CPR) (Annex V) . Bronopol is only used by professional formulators (cosmetics). Registered under REACH as TIER2 substance

	Bronidox is regulated by CPR. It is listed in annex V as approved preservative. Can be used <0.1% in rinse-off cosmetic products. Only used by profesisonal formulators. Will be registered under REACH by 2018 as TIER 3 substance (not manufactured in EU, only imported). **General discussion on releases and exposure (Attachment)** FA releasers can be defined as: • *substances that release formaldehyde as a targeted mode of action OR* • *substances that release formaldehyde as a result of decomposition and/or* • *chemicals synthesized from formaldehyde that may still contain residues of free formaldehyde (e.g.melamine/formaldehyde and urea/formaldehyde resins)* Considerations on exposure : *Bronopol* can release low levels of FA due to its decomposition. These levels are not sufficient to work as biocide therefore Bronopol can not be considered a FA releaser and should be removed from the list of substances (comment to 28 BPR CA meeting -2008). Relevant research studies demonstrate that levels of FA released by Bronopol are so low that the substance cannot be considered a FA relaser. *Bronidox* is produced by reaction between Bronopol and FA. Research studies show that release of FA from Bronidox in typical market products is below the detection limit of 10 ppm.
Company/Italy	**Information on substance and uses** The company informed about the use of 2 FA releasers as preservatives.
Company/United Kingdom	**Information on substance and uses** Formaldehyde being a constituent in the manufacture of a purchased material (PVF) for a critical duplex bonding system used on site. Hydantoin is used as an R & D bonding agent. **General discussion on releases and exposure** Potential release of formaldehyde during curing of PVF (poly vinyl formal), CAS Number 9003-33-2.
Company/Italy	**Information on substance and uses** Paraformaldehyde used as raw material for chemical synthesis
Industry Association/ Germany I&P Europe - Imaging and Printing Association e.V.	**Information on substance and uses** Substances: *CAS no. 52-51-7/Einecs no. 200-143-0: <0,05% in working solutions *CAS no. 5395-50-6/Einecs no. 226-408-0: < 0,15% in working solutions * Bronopol as preservative Part of mixtures are used in photochemicals and pressroom chemicals; e.g. corrosion inhibitor/biocide/alkali , matting agent in coatings, solvent in certain photochemicals, to solve colour developers, pure biocidal

	• In can preservation in working solutions of waterbased mixtures used in offset printing such as pressroom chemicals
Member State/Spain	**Information on substance and uses** Formaldehyde used as ingredient in mixtures used by hairdressers. Reference to an article from America Journal of Industrial Medicine is provided. The article contains information on FA releasers and occurrence of FA releasers in registered chemical products. The attachment contains safety information on FA and technical risk management measures to reduce exposure of workers to FA during industrial use.
Industry Association /Germany Verband TEGEWA e. V.	**Information on substance and uses** Some substances in the list provided by ECHA are use as preservatives for textile and leather chemicals. FA based resins and leather auxiliaries are used to process textiles in industrial settings. (No information on specific substances provided). Clear and unambiguous definition of FA releasers should be provided. **General discussion on releases and exposure** Some resins used in textiles processing, remain on textiles and may release FA. Consumers can be potentially exposed. Limits are established as "non detectable" for children wears, 75 ppm for direct skin contact and 300 ppm for non direct contact to skin and decoration materials. Information on risk assessment (available at TEGEWA) shows that dermal exposure from textile is below no-effect level.
Industry Association/Belgium UEIL (European Association of independent lube manufacturers) and Company/Germany	**Information on substance and uses** FA releasers are used in lubricant (specifically metal working fluids) as biocides. They are subject to BPR. They are listed in BPR as Biocides type 13 (PT13) . The **attachment** contains an extract of the list with the following substances CAS no. (EC no.): 3589-55-8 (222-720-6), 4719-04-4 (225-208-0), 66204-44-2 (266-235-8), 25254-50-6 (246-235-8), 25254-50-6 (246-764-0), 5395-50-6 (226-408-0), 14548-60-8 (238-588-8), 6440-58-0 (229-222-8) with concentration limits for classification and actual classification and labelling. **General discussion on releases and exposure** Use and application of biocidal products are reported in a dedicated table included in the attached document. The document contains, in addition, information on exposure in air in workplace (where metal working fluids are used) showing that the limit recommended by SCOEL (0.2 ppm for FA) is not exceeded in over 95% of measurements provided. Risk management measures are also reported to guarantee safe use.
Company/Germany	**Information on substance and uses** In the lubricants industry formaldehyde releasers are mainly used as biocides in aqueous metal working fluids. Ready-to use emulsions have industrial and professional use, consumer can be excluded. Concentrated substances have only industrial use (preparation of the dilution needs expertise). Typical substances used in lubricants industry are

	Methenami,-Trimethyl-1,3,5-triazin-1,3,5(2H,4H,6H)-triethanol, (Ethylendioxy)dimethanol , 2,2',2''-(Hexahydro-1,3,5-triazin-1,3,5-triyl)triethanol, Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazol-2,5(1H,3H)-dion, N,N'-Methylenbismorpholin, 3,3'-Methylenbis[5-methyloxazolidin]. **General discussion on releases and exposure** In metal working fluids the formaldehyde is used only if there is microbial growth. Under normal use condition, the average concentration of FA in metal working fluid is low (not specified).
Company/Germany	**Information on substance and uses** FA releasers such as hexamethylene tetramine (HMT) or hexamethoxymethyl melamine (HMMM) used in tyre production as adhesives. During the vulcanization process at high temperatures above 150 °C a condensation reaction takes place between in situ released formaldehyde and a phenolic compound (e.g. resorcinol) to form a resorcinol formaldehyde resin which works as adhesive to stick together the rubber with brass coated steel cord or textiles used in rubber manufacturing. The substances can be used as such in powder form, as mixtures or powders and polymer-bound in masterbatches.
Company/Belgium	**Information on substance and uses** 3,3'-Methyleenbis[5-methyloxazolidine], used as biocide in automotive fuels; mixture of 5-chloro-2-methyl-2H-isothiazole-3-one (CAS no. 26172-55-4) and 2-methyl-2H-isothiazole-3-one (CAS no. 2682-20-4); used as preservative in water-based products for automotive applications.
Industry Association/Belgium CIRFS European Man-made Fibres Association	**Information on substance and uses** FA is used in production of tyre cord to improve the bonding of textiles material with rubber during vulcanization. The cord is pre-treated by dipping it into a solution of FA and Resorcinol (RFL-dip Resorcinol, FA, Latex). This FA reacts with Resorcinol during vulcanisation to make a resin. Alternatives to RFL are Penacolite® resin (e.g. R2170), a resorcinol-formaldehyde precondensate. FA is added to Penacolite before reaction. Penacolite® R2170 does not contain any free formaldehyde, so it cannot be considered a FA releaser. Quantity of FA added to dipped cord is very low and FA added to RFL reacts to form the resin. For this reason the likelihood of FA emissions from the cord is considered negligible. FA is considered a crucial compound for tyres cords by tyre industry to meet the safety standard of tyres. In production of man-made fibers one or more substances listed in ECHA's list can be used as biocide. They will be removed in donwstream processes and are not present in final products. Links to Research and market report on FA and FA releasers are provided in the comment.
Industry Association/Belgium Fertilisers Europe	**Information on substance and uses** Formaldehyde is used by fertilizers manufacturers in their products for: Nitrogen slow release fertilizers containing as a component Urea-formaldehyde reaction products. Urea treated with a stabilizer containing urea-formaldehyde reaction products and/or formaldehyde. Treated urea is placed on the market as such, or in mixtures. A list of formaldehyde releasers based on the scientific article of de Groot, A.C. et al. (2009), has been circulated by ECHA and the substance

	Polyoxymethylene urea (INCI)[1] which IUPAC name is *Formaldehyde;urea*, has been included in that list. A clarification on the definition of FA releaser is needed to industry in order to provide correct information.
Company/Spain	**Information on substance and uses (attachment)** FA releasers are used in cosmetics as preservatives. The company uses low amounts of Imidazolidinyl urea (CAS no. 39236-46-9) and Sodium hydroxymethylglycinate (CAS no. 70161-44-3) **General discussion on releases and exposure** Cosmetic ingredients are used by professional users. Products (mixtures) are used by consumers. Information is provided on national OELs (related to a single EU Member State) on typical risk management measures used to control exposure to workers.
Industry Association/Belgium Plastics Europe	**Information on substance and uses** ParaFA is listed as FA releaser in ECHA's document with CAS no. 30525-89-4 with common name Polyoxymethylene (POM). POM is also the IUPAC name of ParaFA for typical degree of polymerisation of 8-100 Units. In the opinion of the writer , higher grades of polymerisation of termoplastic Polyoxymethylenes do not intentionally release FA and should not be included in the list of FA releaser. The industry association is asking ECHA to clarify that the compounds listed under CAS No. 30525-89-4 refers only to polyoxymehylenes with degree of polymerisation 8-100.
Company/Germany	**Information on substance and uses** ParaFA is used as intermediate to produce the following FA releasers: Diazolidinyl urea, DMDH: used as perservatives in rinse off cosmetic products. MBO, HPT, TMAD: biocidal use only **General discussion on releases and exposure** Release of FA from FA releasers occurs in different way than release of FA from a FA solution. In absence of water FA is not expected to be relased from FA releasers. In high diluted aqueous systems, FA is released slowly directly onto the matrix. In the case of FA solution, the complete amount of FA is available directly.
Industry Association./Belgium ETRMA (European Tyre and Rubber Manufacturers Association)	**Information on substance and uses** Hexamethylenetramine HMT (CAS no. 100-97-0) is used as reinforcing agent / hardener in the manufacturing of tyres and certain general rubber goods. It is also used as methylene donor in the rubber-to-textile bonding system. 1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde, methylated HMM (CAS no. 68002-20-0) is known to be used for the same uses as HMT but it cannot fully replace HMT in all applications. Information is provided on melamine-condensed resins and phenolic resins produced from FA. These resins are mostly used as adhesives in tyre manufacturing to increase the strength and safety of tyres. **General discussion on releases and exposure**

	Measurements of workers exposure to formaldehyde are conducted by the industry in the workplaces to ensure that exposure limits remain below existing Occupation Exposure Limits. However, it must be noted that these measurements do not allow us to distinguish the source of formaldehyde.
Company/Germany	**Information on substance and uses** Ethylene urea (CAS no. 120-93-4). Substance is not a formaldehyde releaser, but it is formaldehyde scavanger. The purpose is to reduce residual FA by chemical reaction, which is opposite of the FA releasers. **General discussion on releases and exposure** FA is not even used in the synthesis. Skin sensitising potential studied, and the substance does not have even a weak skin sensitisation potential. FA impurity results from residual FA monomer in the resin which was not scavenged by ethylene urea. De Groot definition cannot be used for REACH. Under Biocides regulation there is a regulatory definition already. Chemical synthesis has been forgotten and wrong conclusions used, e.g. dimethylglyoxal urea, glyoxal urea and ethylene urea are incorrectly said to be FA releasers.
Company/Germany	**Information on substance and uses** N,N-dimethyl 4,5-dihydroxyethylene urea (CAS no. 3923-79-3) **General discussion on releases and exposure** Substance is not a FA releaser, not able to release FA, no FA used in the synthesis. One of the raw materials (glyoxal) may contain up to 100 ppm FA as impurity, but it does not survive in the synthesis. Substance is a possible FA free alternative in textile finishing.
Industry association/Belgium Toy Industries of Europe	**Information on substance and uses** a. 4,4-dimethyloxazolidine (CAS no. 51200-87-4) b. 5-ethyl-3,7-dioxa-1-azabicyclo[3.3.0]octane (CAS no. 7747-35-5) c. 2-bromo-2-nitropropane-1,3diol (CAS no. 52-51-7) d. Diazolidinyl urea (CAS no. 78491-02-8) e. DMDN hydantoin (CAS no. 6440-58-0) f. Formaldehyde (CAS no. 50-00-0) g. Imidazolidinyl urea (CAS no. 39236-46-9) h. Methanamine (CAS no. 100-97-0) i. Paraformaldehyde (CAS no. 30525-89-4) j. Formaldehyde urea (CAS no. 9011-05-6) k. Quaternium 15 (CAS no. 4080-31-3) l. Sodiumhydroxymethylglycinate (CAS no. 70161-44-3) **General discussion on releases and exposure** Information provided on the permitted uses in toys, e.g. in finger paints as leave on preservatives (EN standard available). FA not used directly in toy, but low concentrations may be present as a release

	from other substances and materials. Formaldehyde urea may be present as a bonding agent in urea formaldehyde (UF) resin manufactured board, such as plywood, particle board and medium density fibreboard (MDF). FA release as unintentional. For toy mixtures individual exposure to FA from the use of FA releasers would not be expected to exceed that for cosmetic usage. Exposure less than with cosmetics; occasional use and not applied to the body in majority of the cases.
Member State/Germany	**Information on substance and uses** Tables in ECHAs background document was used as a basis to provide information. **General discussion on releases and exposure** Table 1 A and B: information on cosmetic ingredients provided. Table 2 and 3: table updated with specific names and CAS numbers and references to Table 1. For calculation of exposure it is adviced to note the SCCSs guidance document for the testing of cosmetic ingredients and their safety evaluation. Concerning toys, different standards are referred. In addition information from an investigation on preservatives in finger paints and slimes by food control agencies in Germany (2013) is provided.
Company/Belgium	**Information on substance and use** Methylal (dimethoxymethane; CAS no. 109-84-5) Substance can be used in a chemical synthesis as a source of FA, but as such propably not used. The uses are in coating products, cleaning products, fuels, lubricants, greases and hair care products. It is also used for the manufacture of chemicals. **General discussion on releases and exposure** Various grades of methylal in commerce contain only trace of unreacted FA. The reply provides information on methylal metabolism and discusses FA formation in the body after exposure.
Company/the Netherlands	**Information on substance and use** Ethylene Urea, Imidazolidin-2-one (CAS no. 120-93-4) **General discussion on releases and exposure** In literature, the substance is a FA scavenger where ethylene urea binds with free FA and not FA releaser. Company uses ethylene urea to actively reduce and remove free FA from certain production processes.
Company/Germany	**Information on substance and use** Tris(N-hydroxyethyl)hexahydrotriazine (CAS no. 4719-04-4) – non biocidal use **General discussion on releases and exposure** Definition by de Groot is misleading and too broad to be used in the regulatory context of REACH. FA releaser should be used only in the context of preservatives/biocides. De Groot's definition includes substances with an unwanted remaining FA impurity deriving from the chemical synthesis. There are

	some classes of substances generally identified as FA releasers. However, there are urea derivatives that are able to release FA but some are not. E.g. ethylene urea is a FA scavanger but not a releaser. Substance mentioned above is applied as scavanger for sulphide in refinery and/or oilfield application. The residual concentration of free FA in this product is far below 100 ppm. The product is an aqueous formulation with pH of ca. 10, when it is stable over months without any decomposition or degradation. During application the product reacts, but no FA released. The product is not intended for end-consumer uses.
Industry association/Belgium Formaldehyde Biocide Interest Group (FABI)	**Information on substance and uses** Formaldehyde releasers constitute an essential category of biocidal active substances. The uses are fully controlled under the scope of the BPR. **General discussion on releases and exposure** CA-Febr08-Doc.8.4 28th meeting of MSCAs for biocidal products (Conclusion of a workshop on FA releasers, held in Warsaw on 14-15 January 2007): "The activity of bronopol is actually not dependent on formaldehyde release but in microbial cells is partly based on the reaction of the bronobol molecule with thiol groups and by the formation of oxygen radicals." Due to this mode of action it was agreed that bronobol was excluded from the group of FA releasers. CA-March15-Doc.5.1-Final, revised on 23 June 2015 (biocides): FA releaser belong to the so called Active Substance Releasers which are defined as follows: "Active substance releasers are substances which upon use release a substance, which has a biocidal activity. For such substances, no other precursor is required, the reaction is taking place under certain conditions and not necessarily at the place of use. The substance released and the substance releaser shall be regarded as the active substance and be managed as such. Furthermore, the name of the active substance will be the combination of the names of the substance released and of the substance releaser (e.g. Formaldehyde released from N,N'-methylenebismorpholine). This name will be used for the substance approval as well as for the purpose of Article 95 listing." Reply provides information on FA releasers as biocides. Regarding other uses of FA releasers than biocidal uses, the association is not in a position to provide further information on the REACH or cosmetic uses. The relevant REACH registrants should be addressed for collecting such information. Clarifications on the tables in ECHAs' background document provided.
Industry association/Belgium	**Information on substance and uses** The association invites ECHA to provide definition of FA releasers. Definition by de Groot is too broad in the regulatory context of REACH and is misleading. FA releaser is used in the context of biocidal regulation, de Groot definition includes substances with an unwanted remaining FA impurity, review neglects current routes of chemical synthesis and draws wrong conclusions from chemistry perspective,

European Polymer Dispersion and Latex Association (EPDLA)	e.g. ethylene urea is a FA scavenger, from a medicinal perspective the source of the FA may not be relevant, FA releasers that are biocides should be removed from the list.
Industry association/Belgium Cosmetics Europe	**Information on substance and uses** Only FA releasers listed as authorised preservatives (antimicrobial protection) in Annex V of the Cosmetic Regulation are used by cosmetic industry. All FA releasers listed in Annex V of the Cosmetic regulation are also listed in the tables of the ECHA background note. **General discussion on releases and exposure** Restrictions shall not apply to uses in cosmetic products (human health criteria only). Carcinogenic effects of FA were observed following exposure via the inhalation route. Inhalation exposure represents an insignificant fraction of the total human FA exposure from other sources. Therefore FA released by formaldehyde releasers used in cosmetics poses no or negligible risk to human health.
Industry association/Belgium European Federation for Cosmetic Ingredients (EFfCI)	**Information on substance and uses** Approved formaldehyde releasing preservatives are included in the Cosmetics Regulation, Annex V. The comment provides also information on the need to use preservatives in cosmetics.
Company/Germany	**Information on substance and uses** Typical application is preservative for the manufacturing of cosmetic products. They do not have other substances that are FA releasers apart from substances mentioned in ECHAs' background note. **General discussion on releases and exposure** The exposure of the workers to FA is measured and national limits are kept.
Member State/Sweden	**Information on substance and uses** KEMI has published two reports which might be relevant for ECHA's study: one on hazardous chemicals in textiles and one on hazardous chemicals in construction products . Attachment provides lists of substances in the reports in excel-format, in order to make comparison of the substances to those identified by ECHA. **General discussion on releases and exposure** Textile articles and construction products are product categories were FA releasers may be used and were release of FA is a well known problem.
Company/the Netherlands	**Information on substance and uses** Company is an importer and REACH Registrant of three cosmetic preservatives. These substances are listed in the Cosmetics Regulation, Annex V.

	Bronobol should not be considered as a formaldehyde releaser according to clarifications by the authorities under BPR. This is also applicable to its use as a preservative in cosmetic products. Bronobol's mode of action is not related to formaldehyde release. **General discussion on releases and exposure** Inhalation exposure to formaldehyde to consumers from the use of cosmetic procucts is insignificant compared to formaldehyde exposure from other sources (reference to a specific study from 2012). Exposure of workers to formaldehyde during processing and handling of these FA releasers is negligible (based on quantitative 13C-NMR analysis).
Company/Belgium	**Information on substance and uses** Mixtures and articles containing many of the substances identified in the background note are used in the production and maintenance of aerospace products. Specific funtions can be as to control microbial growth, or as constituents of binding agents in primers, topcoats, adhesives and inks as well as in abrasive media for stripping organics and mechanical surface preparation. It is possible that other substances which may be considered as FA releasers are used in aerospace products, however it is challenging to understand how the substances meet the criteria to be considered FA releasers. They are downstream user and limited to use safety data sheeet (SDS) to identify specific substances, and to consult formulators to understand e.g. the actual function of the substance. Substances may be constituents in base polymers, binders, or chemical treatments of textiles, insulation blankets, foams, and felts used in ducks, sidewall panels and floors, and other interior support structures. Resins are critical for meeting EASA flammability requirements. Articles may be imported in aircraft and other aerospace products, including as spare parts.
Company/United Kingdom	**Information on substance and uses** Provides information on company's use of FA donors in detergents. DMDM hydantoin is used as a preservative in liquid laundry detergents and hand dishwash detergents. **General discussion on releases and exposure** Inhalation exposure to formaldehyde to consumers from the use of cosmetic procucts is insignificant compared to formaldehyde exposure from other sources (reference to a specific study from 2012). Application of detergents would be further from the breathing zone versus a shampoo or facial moisturiser, thus the use of the substance in detergents can be considered as safe for human health.

Comments received via e-mail	
Submitter/Country	**Summary of the comment**
Industry association/Belgium Formacare	**Information on substance and uses** *Urea formaldehyde (UF) resins (CAS no. 9011-05-6)* Used as cross linkers in production of thermosetting adhesives that are further used in production of particle boards, MDF and plywood. Cross linkers are mixed with other components of the adhesive before end use. *Melamine formaldehyde (MF) resins (CAS no. 9003-08-1)* Similar properties to UF resins, but they are tougher and more thermally stable and chemically resistant. MF resins are used for wood adhesives and higher end applications like laminates for countertops and cabinets (over 75%). Those resins are also used for surface coatings for automobiles (less than 10%) that require a binder with good cosmetic characteristics. *Paraformaldehyde (CAS no. 30525-89-4)* High-formaldehyde-content solid that is available as 91% or 95% prills. It is mainly used as transported isolated intermediate in chemical synthesis of resins and substances. Used by resin manufacturers seeking low water content or more favourable control of reaction rates when compared to aqueous formaldehyde solutions. *Hexamine (CAS no. 100-97-0)* Mainly used as transported isolated intermediate in chemical synthesis of resins and substances. It is a white, hygroscopic, crystalline solid, is used as a curing agent in phenolic and epoxy resins. It is also used in the production of explosives. **General discussion on releases and exposure** Formaldehyde is unintentionally released during the curing phase (end use of the resin). FA emissons are expected and exposure to workers is controlled by mean of Local Exhaust Ventilation and personal protective equipments. Risk assessment study conducted by TNO and RPA in 2013. The study covers the exposure to workers during manufacturing of FA based resins and their uses downstream. Safe use has been defined for exposures before the DNELs set by REACH FA consortium as 0,5 mg/m3 (inhalation long term) and 1 mg/m3 (inhalation short term). Measured data are available for manufacturing and relevant DU uses. For use in paints sufficient number of measurement data are available. For other DU uses, when measured data were not available, model extimation has been use to define appropriate risk management measures Models used were Tier 1 tool EASY TRA (V 3.5.0 with ECETOC TRA V3 built in) and ART 1.0 (higher Tier tool). Models were used to

	assess dermal exposure. Exposure to workers is analysed for FA production (long term 90th percentile and short term 95th percentile). Data show that long term exposure to workers is below DNEL (personal measurements) while stationary measurements show exposure above DNEL. General ventilation , closed systems and Local Exhaust Ventilation are taken in to account when exposure is measured. For maintenance and cleaning activities (short term) also PPEs (RPE) with RF of 10 are assumed. It has to be considerd that in both cases measurements take into account FA released from process as well as background level of FA already present (e.g. from other sources like combustion, natural phenomena etc). Short term exposure is kept below DNEL if PPE with RF 10 are used. Note these type of measurement do not take into account peak exposure to FA which can be higher than DNEL (short term) in the short range. Exposure to workers during transfer of FA and resins (still manufacturing Life Cycle) and exposure to workers in labs has been also assessed. Also in this case exposure is below DNELs (long term and short term) if appropriate risk management measures such as Local Exhaust Ventilation general ventilation and PPE (short term), are used. Analysis of workers exposure measured data in manufacturing of resins show that both for long term and short term exposure, DNELs are exceeded. Exposure to workers performing control activities (including sampling) in resins manufacturing process, show that DNEL is not exceeded for long term exposure, while it is slightly exceeded in the short term exposure. Workers exposure in wood panels production is <<DNEL for both long and short term exposure. In paper impregnation and lamination of wood based panels, exposure to workers is <DNEL for long term and short term exposure. Workers exposure in sanding and sawing of wood based panels is also <DNEL. Other uses of FA based product – formulation of FA based products, production of fertiliser granules, production of tyre and rubber products, production of leather products and production of foams, fibers and mats, are also below DNEL for long and short term exposure. In all uses general ventilation, Local Exhaust Ventilation are assumed as risk management measures. Information on workers exposure in various process from literature data are also reported, but they are not considered fully reliable. Uses by professional workers have been assessed using models showing that workers exposure exceed DNELs in production of foam and use resin wood application if stringent risk management measures are not used. In all industrial uses (manufacturing of FA and FA resins and use of FA resins), workers exposure is below DNELs assuming adequate risk management measures are used: i.e. Local Exhaust Ventilation, general ventilation, closed system (manufacturing and transport) and personal protective equipments (short term).
Medical association/Belgium European Society of Pathology UEMS	**Information on substance and uses** Use of formalin in pathology in sample treatment. This type of analysis is key in cancer diagnosis. The association is concerned over posible ban of Formalin in 2016 as no suitable alternatives are availble to replace formalin in sample tissues preservation. Even when alternatives can be considered, they should be validated to guarantee reproducibility and this process is long and very complex. At moment no suitable reproducible alternative has been identified. Higher costs for EU healthcare system has to be

	taken into account if alternatives to formaline (cheap chemical) have to be developed and used to replace formaline in pahtology applications. The association asks exemptions from ban of formaline for use in the EU health system. **General discussion on releases and exposure** Formalin is used in laboratory settings and risk management measures are already in place (i.e. LEV and PPEs) to prevent exposure. These measures can be further improved (e.g. vacuum treatment and closed system).
Company/Germany	**Information on substance and uses** Ethylene Urea (Imidazolidin-2-on)(CAS no. 120-93-4). The author claims that Ethylene Urea is not a FA releaser, but is considered a FA scavenger. This substance is included in the list by De Groot in group A (substances considered as FA releasers "confirmed by scientific evidence"). Evidence provided from other users of the same substance. The writer asks ECHA to consider whether such substance should not be included in the list of FA releasers.
Company/Germany	**Information on substance and uses** *Melamine Formaldehyde Sulfonate, MFS resins* Polyoxymethylene melamine (INCII), CAS no. 64787-97-9, Sulfurous acid, sodium salt (1:1), polymer with formaldehyde and 1,3,5-triazine-2,4,6-triamine Used in construction chemicals. MFS resins are sulfite modified, melamine formaldehyde condensation products. These raw materials are especially suitable for flowing concrete and are distinguished by their good compatibility with cement. Available in aqueous solutions and free flowing spray dried products in powder form. MFS products in powder form are used for the improvement of workability (plastification), water reduction and increased strength development of dry mortars based on cement or calcium sulphate. Typical applications are: self-levelling underlayments (SLU), feather-edge products, non-shrink grouts, floor screeds, self-levelling floor screeds, tile adhesives and joint fillers, repair mortars, injection mortars and dry-mix concrete. **General discussion on releases and exposure** MFS may contain up to 0.3% of free FA which is reduced to <0.1% (CLP: not classified) in novel types of products with the addition of FA scavengers such as Ethylene Urea. Resins usage in construction material is very low (around 0.1% in weight) and risk of workers exposure is minimal.
Company/United Kingdom	**Information on substance and uses** DMDM Hydantoin, (DMDMH) CAS no. 6440-58-0 This formaldehyde releaser (FR) is used almost exclusively as a preservative. The uses fall within the scope of two regulatory regimes the BPR and the Cosmetic Regulation. For Biocidal (BPR) applications DMDMH is supported for both PT6 and PT13. **General discussion on releases and exposure**

	Information from cosmetic industry report exposure < 0.1mg/m3.
Company/United Kingdom	**Information on substance and uses** Sodium oxymethylene sulfoxylate (INCI) CAS no. 149-44-0 and EC no. 205-739-4 It is listed as a reducing agent in the EU Cosmetic Directive but is not recognised as a formaldehyde producer. Historically this chemical has been used in the textile industry for over 100 years to decolour dyes on fabric and is widely known to produce formaldehyde, both within the industry and in the scientific literature. As such it is used only under strict safety procedures. During use the compound, which is a stable crystalline solid, is mixed with an acid. This produces the reducing species together with equal amounts of formaldehyde. For a number of years now the chemical has also been used in a growing number of hair dye colour removal products, both within the EU and Worldwide. Typically such products contain the above compound in the 5-10% range and consist of two components: a bottle containing the above chemical and an acidic cream, to be mixed together before application to the head.