

## Call for evidence on the use of formaldehyde releasers on their own, in mixtures or in articles by workers, professionals and consumers

### Background document

#### *Objective*

To gather information for the investigation report on the uses of formaldehyde releasers which will be used to support the Commission's decision if a preparation of an Annex XV restriction dossier on formaldehyde and formaldehyde releasers is warranted. Information from as many relevant stakeholders as possible is needed and includes information on uses and tonnages, in the first place, but also information on emissions and exposures of formaldehyde releasers included in tables 1-3 below in this document can be submitted. Also information on other formaldehyde releasers than identified so far (see tables included in this document) is needed.

This call for evidence targets interested parties such as companies (manufacturers, suppliers, distributors, importers etc.), trade associations and any other stakeholders or Member State Authorities holding relevant information. Specific questions are addressed on certain issues of particular interest.

Therefore, anyone who could be affected by this possible restriction or who holds relevant information is kindly invited to provide responses before 4 October 2016.

For any clarifications on completing the questionnaire, please contact the ECHA Restriction Formaldehyde group at [echa-restriction-formaldehyde@echa.europa.eu](mailto:echa-restriction-formaldehyde@echa.europa.eu).

#### *Background*

On 3 December 2015, ECHA received a request by the European Commission to investigate formaldehyde releasers and their uses in the EU (see: [http://echa.europa.eu/documents/10162/13641/echa\\_annex\\_xv\\_restriction\\_proposals\\_en.pdf](http://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf)).

ECHA is currently investigating possible formaldehyde releasers and their use in the EU with the aim to support the EU Commission to decide whether to request ECHA to prepare an Annex XV dossier for restriction on formaldehyde and whether formaldehyde releasers should be part of this restriction dossier.

Formaldehyde is harmful to human health. The current harmonised classification for formaldehyde according to CLP Regulation (Regulation EU No 1272/2008) is Carcinogenic 1B, Mutagenic 2, Acute Tox. 3 (inhalation, contact with skin, oral), Skin Sensitiser 1 and Skin Corrosive 1B. Moreover, ECHA's Committee for Risk Assessment has issued opinions on three formaldehyde releasers in regards their classification and labelling (see table 2).

Formaldehyde is included in the Community Rolling Action Plan (CoRAP). The evaluation of the substance was a joint activity performed by France (leading the evaluation) and the Netherlands, where France was responsible for addressing concerns to workers and the Netherlands had the responsibility for addressing concerns for consumers and general population.

Based on the evaluation, ECHA has decided on 6 October 2015 to request the registrants of formaldehyde to provide further information regarding the registered substance and where relevant, to update their Chemical Safety Report, especially the exposure scenarios covering use by consumers. The deadline for submitting the information to ECHA is by 13 October 2017 (see ECHA's decision: [Formaldehyde - Substance evaluation - CoRAP - ECHA](#) ).

In September 2015 France announced its intention to prepare an analysis of the most appropriate risk management option (RMOA) for the substance (see the intention: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/10309/term>). France launched a public consultation on the RMOA on formaldehyde on 7 July 2016: <http://www.consultations-publiques.developpement-durable.gouv.fr/consultation-publique-sur-le-rapport-de-l-anses-a1421.html>

ECHA's current investigation on formaldehyde releasers aims also to support France and the Netherlands in their work with formaldehyde.

Formaldehyde 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. See further information: [http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\\_id=8299](http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299).

Simultaneously with this call for evidence, ECHA is making a screening of the registration dossiers. ECHA's investigation of formaldehyde releasers begins with the substances listed as formaldehyde releasers in the Annex V of the Cosmetic Product Regulation 1223/2009. Furthermore, ECHA continues to investigate formaldehyde releasers included in table 2 of the scientific article by de Groot A.C. et al. (2009) <http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0536.2009.01582.x/epdf>.

Additional investigation is made on substance identified as formaldehyde releasers in biocidal review (table 3 extracted from formaldehyde releasing biocidal active substances included in the Commission delegated Regulation (EU) No 1062/2014 (the Review Programme Regulation)).

**Table 1: List of formaldehyde releaser based on the scientific article of de Groot, A.C. et al. (2009).**

(A) Chemicals for which adequate clinical data are available to identify them as formaldehyde-releasers beyond doubt

Commonly used name	IUPAC name	Other synonyms	Current trade names <sup>i</sup>	CAS number
Benzylhemiformal (INCI) <sup>*</sup>	Phenylmethoxymethanol	(Benzyloxy)methanol	Akyposept <sup>®</sup> B [Preventol <sup>®</sup> D2; See there]	14548-60-8
Bioban CS 1135 <sup>®</sup>	4,4-Dimethyloxazolidine; 3,4,4-trimethyloxazolidine		Bioban CS 1135 <sup>®</sup>	81099-36-7 (ingred. 75673-43-7 and 51200-87-4)
Bioban CS 1246 <sup>®</sup>	5-Ethyl-3,7-dioxo-1-azabicyclo[3.3.0]octane	7-Ethylbicyclo-oxazolidine	Bioban CS-1246 <sup>®</sup> Chemtan A60 <sup>®</sup> Oxazolidine-E <sup>®</sup> Zoldine ZE <sup>®</sup>	7747-35-5
Bioban P-1487 <sup>®</sup>	4-[2-(Morpholin-4-ylmethyl)-2-nitrobutyl]morpholine; 4-(2-nitrobutyl)morpholine	Mixture of nitrobutylmorpholine and ethylnitrotrimethylenedi morpholine	Bioban P-1487 <sup>®</sup>	37304-88-4 (ingred. 1854-23-5 and 2224-44-4)
2-Bromo-2-nitropropane-1,3-diol (INCI) <sup>**</sup>	As in column 1	Bromonitropropanediol; Bronopol	Bronopol <sup>®</sup> ; Chemynol BP <sup>®</sup> ; Myacide Pharma BP <sup>®</sup> ; Onyxide 500 <sup>®</sup>	52-51-7
Diazolidinyl urea (INCI) <sup>*</sup>	1-[1,3-bis(hydroxymethyl)-2,5-dioxo-imidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea	<i>N,N'</i> -bis(hydroxymethyl)urea	Abiol Forte <sup>®</sup> ; Germall II <sup>®</sup> ; Liposerve DU <sup>®</sup> ; Nipa Biopure 200 <sup>®</sup>	78491-02-8
Dihydroxydimethylolethyleneurea, methylated	4,5-Dihydroxy-1,3-bis(hydroxymethyl)-imidazolidin-2-one, methylated	Dimethylolglyoxalurea, methylated	Fixapret <sup>®</sup> (various); Freerez PKF <sup>®</sup> ; Knittex LE <sup>®</sup> ; Permafresh <sup>®</sup> (various); Sumitex <sup>®</sup> (various)	68411-81-4
1,3-Dimethyl-4,5-dihydroxyethyleneurea	4,5-Dihydroxy-1,3-dimethylimidazolidin-2-one		Fixapret NF <sup>®</sup>	3923-79-3
Dimethylhydantoin formaldehyde resin <sup>***</sup>	5,5-Dimethylimidazolidin-2,4-dione, formaldehyde	Formaldehyde, polymer with 5,5-dimethyl-2,4-imidazolidinedione; DMHF		26811-08-5

Commonly used name	IUPAC name	Other synonyms	Current trade names <sup>i</sup>	CAS number
Dimethyloldihydroxyethyleneurea	4,5-Dihydroxy-1,3-bis(hydroxymethyl)-imidazolidin-2-one	1,3-Bis(hydroxymethyl)-4,5-dihydroxy-2-imidazolidinone	Fixapret <sup>®</sup> (various); Permafresh <sup>®</sup> (various)	1854-26-8
Dimethylolethyleneurea	1,3-Bis(hydroxymethyl)imidazolidin-2-one		Fixapret AH <sup>®</sup>	136-84-5
Dimethylolpropyleneurea	1,3-Bis(hydroxymethyl)-1,3-diazinan-2-one	DMPU; Tetrahydro-1,3-bis(hydroxymethyl)-1H-pyrimidin-2-one	Fixapret PH <sup>®</sup> ; Knittex PRS <sup>®</sup>	3270-74-4
Dimethylol urea (INCI)	1,3-Bis(hydroxymethyl)urea	<i>N,N'</i> -Bis(hydroxymethyl)urea; Carbamol; Dihydroxymethylurea; <i>N,N'</i> -dimethylolurea; Dimethylurea; Oxymethurea (MI); Urea formaldehyde	Kaurit S <sup>®</sup> ; Methural <sup>®</sup> ; Permafresh 477 <sup>®</sup> ; Urofix <sup>®</sup>	140-95-4
DMDM hydantoin (INCI) <sup>**</sup>	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	Dimethyloldimethylhydantoin; 1,3-dimethylol-5,5-dimethylhydantoin; DMDMH	Cosept DM <sup>®</sup> ; Dekafald <sup>®</sup> ; Glydant <sup>®</sup> (2000, XL-1000); Lanodant DM <sup>®</sup> ; Mackstat DM <sup>®</sup> ; Microcare DH <sup>®</sup>	6440-58-0
Ethylene urea	Imidazolidin-2-one	2-Imidazolidinone (MI); 2-Oxoimidazolidine		120-93-4
Forcide 78 <sup>®</sup> I <sup>ii</sup>	(Z)-3-(Bis(2-hydroxyethyl)amino)-2-(2-hydroxyethyl(hydroxymethyl)amino)prop-2-en-1-ol	2-Hydroxymethylamino-ethanol-tri- <i>N</i> -ethylhydroxy-2-amino-methylene	Forcide <sup>®</sup> 78 <sup>iii</sup>	77044-78-1
Forcide 78 <sup>®</sup> II <sup>iv</sup>	1,3,5-Triethyl-1,3,5-triazinane (b)	(b) Hexahydro-1,3,5-triethyl- <i>s</i> -triazine; (b) Triethyl-trimethylenetriamine mixture of (a) triazinetriethanol (see there) and (b) hexahydro-1,3,5-triethyl-1,3,5-triazine	(b) Vancide-TH <sup>®</sup> ; Forcide <sup>®</sup> 78 <sup>v</sup>	7779-27-3 (b)
Formaldehyde (INCI, MI) <sup>*</sup>	Formaldehyde	Formalin; Methanal; Methyl aldehyde; Oxymethylene		50-00-0
Glyoxalurea	4,5-Dihydroxyimidazolidin-2-one	Dihydroxyethyleneurea; Glyoxalmonoureine		3720-97-6

Commonly used name	IUPAC name	Other synonyms	Current trade names <sup>1</sup>	CAS number
Imidazolidinyl urea (INCI, MI)*	3-[3-(Hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1-[[[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl] carbamoylamino]methyl]urea	Bis(methylolhydantoin urea) methane; Imidurea (MI)	Germall 115 <sup>®</sup> ; Liposerve IU <sup>®</sup> ; Nipa Biopure 100 <sup>®</sup> ; Protacide U-13 <sup>®</sup> ; Unicide U-13 <sup>®</sup>	39236-46-9
MDM hydantoin (INCI)	1-(Hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	1-Hydroxymethyl-5,5-dimethyl hydantoin (MI); MDMH; Methylol dimethyl hydantoin; Monomethylol dimethyl hydantoin	Glycoserve <sup>®</sup>	116-25-6
Methenamine (INCI, MI)**	Not available	Aminoform; Formamine; Hexamethylene tetramine; Hexamine; Methenamide	Cystamine <sup>®</sup> ; Urotropine <sup>®</sup> ; Vulkacit H30 <sup>®</sup>	100-97-0
<i>N,N'</i> -Methylenebis(5-methyloxazolidine)	5-Methyl-3-[(5-methyloxazolidin-3-yl)methyl]oxazolidine		Grotan OX <sup>®</sup>	66204-44-2
4,4'-Methylenedimorpholine	4-(Morpholin-4-ylmethyl)morpholine	Bismorpholinomethane; Dimorpholinomethane; 4,4'-methylenebis-morpholine		5625-90-1
<i>N</i> -Methylolchloracetamide	2-Chloro- <i>N</i> -(hydroxymethyl)acetamide	Chloroacetamide- <i>N</i> -methylol	Grotan DF-35 <sup>®</sup>	2832-19-1
Methylol urea	Hydroxymethylurea	<i>N</i> -(hydroxymethyl)urea; Methyl hydroxyurea; Mono(hydroxymethyl)urea; Monomethylolurea;		1000-82-4
Paraformaldehyde*	Formaldehyde	Paraform; Poly(oxymethylene)	Aldacide <sup>®</sup> ; Formagene <sup>®</sup>	30525-89-4
Polyoxymethylene melamine (INCI)**	Not available	Melamine, polymer with formaldehyde; Melamine/formaldehyde resin; Nanoplast		9003-08-1
<i>Polyoxymethylene urea</i> (INCI)**	<i>Formaldehyde; urea</i>	Polynoxylin; Urea-formaldehyde resin;	Karbamol <sup>®</sup> (B/M); Kaurit <sup>®</sup> (285FL, 240); Uformite <sup>®</sup>	9011-05-6

Commonly used name	IUPAC name	Other synonyms	Current trade names <sup>i</sup>	CAS number
		Urea, polymer with formaldehyde		
Preventol D2 <sup>®vi</sup>	Phenylmethoxymethoxy- Methylbenzene	Bis(benzyloxy)methane; Mixture of hydroxymethylene and polyhydroxymethylene monobenzylether; 1,1'-(Methylenebis(oxyethylene)) bis-benzene	Preventol D2 <sup>®</sup> . This trade name is also often used for benzylhemiformal	2749-70-4
Propyleneglycol hemiformal	Not available			
Quaternium-15 (INCI, MI) <sup>**</sup>		N-(3-Chloroallyl)hexaminium chloride; Chloroallylhexaminium chloride; 1-(3-Chloroallyl)-3,5,7-triaza-1-azonia- adamantane chloride; Hexamethylene tetramine chloroallyl chloride	Cosept 200 <sup>®</sup> ; Dowicide Q <sup>®</sup> ; Dowicil <sup>®</sup> (75, 200)	4080-31-3
Sodium hydroxymethylglycinate (INCI) <sup>*</sup>	Not available	Glycine, N-(hydroxymethyl)-, sodium salt (1:1); N-hydroxymethylglycine (mono)sodium salt; Sodium N-(hydroxymethyl)glycinate	Suttocide A <sup>®</sup>	70161-44-3
Tetramethylol acetylenediurea	2,4,6,8-Tetrakis(hydroxymethyl)- 2,4,6,8-tetraazabicyclo[3.3.0]octane-3,7-dione	Tetrakis(hydroxymethyl) glycoluril; Tetramethylolglycoluril	Fixapret 140 <sup>®</sup>	5395-50-6
Tris(N-hydroxyethyl) hexahydrotriazine	2-[4,6-Bis(2-hydroxyethyl)1,3,5-triazinan-2-yl]ethanol	Hexahydro-1,3,5-tris(hydroxyethyl) triazine; Triazinetriethanol; Trihydroxyethylhexahydro s-triazine; 1,3,5-Trihydroxyethylhexahydrotriazine	Forcide 78 <sup>®</sup> (see there); Grotan <sup>®</sup> (B, BK, HD); Onyxide 200 <sup>®</sup> ; Roksol T 1-7 <sup>®</sup>	4719-04-4
Tris(hydroxymethyl)-nitromethane (INCI, MI)	2-(Hydroxymethyl)-2-nitropropane- 1,3-diol	Nitromethylidynemethanol; Trimethylolnitrometh	Tris Nitro <sup>®</sup>	126-11-4

Commonly used name	IUPAC name	Other synonyms	Current trade names <sup>i</sup>	CAS number
		ane; Tris nitro		

\* 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](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"

\*\*\* resins (formaldehyde is used as a starting material in the chemical industry for the production of condensed resins)

<i>(B) Chemicals for which adequate clinical data are lacking to identify them as formaldehyde-releasers beyond doubt</i>				
5-Bromo-5-nitro-1,3-dioxane (INCI) <sup>**</sup>	5-Bromo-5-nitro-1,3-dioxane	Bromonitrodioxane	Bronidox <sup>®</sup> ; Dekasol <sup>®</sup> 5 & 10	30007-47-7
1,6-Dihydroxy-2,5-dioxahexane	2-(Hydroxymethoxy) ethoxymethanol	Dimethylol glycol; 2,5-Dioxahexane-1,6-diol; (Ethylenedioxy)dimethanol; Ethyleneglycoldiformal	Descocide 9 <sup>®</sup> ; Nipacide FC <sup>®</sup>	3586-55-8
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-imidazolidinemethanol		16228-00-5
Methylal (INCI, MI)	Dimethoxymethane	2,4-dioxapentane; Formal; Formaldehyde dimethyl acetal	Anesthenyl <sup>®</sup>	109-87-5
N-Methylethanolamine	2-(Hydroxymethylamino)ethanol		Troysan 174 <sup>®</sup>	34375-28-5

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

**Table 2: Formaldehyde releaser for which the Committee for Risk Assessment has adopted opinions on harmonised classification**

Name of the substance	Reference
4,4'-methylenedimorpholine [MBM]	<a href="http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12647/term">http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12647/term</a>
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); [MBO]	<a href="http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12646/term">http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12646/term</a>
Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1); [HPT]	<a href="http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12645/term">http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/12645/term</a>

**Table 3: Formaldehyde releasers in the biocidal review**

Entry numbers in the Review Programme Regulation	Substance	Remarks
359	(ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	
368	Methenamine 3-chloroallylochloride (CTAC)	Already in table 1 (CAS no: 4080-31-3)
377	2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (HHT)	
393	1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH)	Already in table 1 (CAS no: 6440-58-0)
797	cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis CTAC)	
444	7a-ethylidihydro-1H,3H,5H-oxazolo[3,4-c]oxazole (EDHO)	
531	(benzyloxy)methanol	Already in table 1 (CAS no: 14548-60-8)
566	.alpha.,.alpha.',.alpha."-trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (HPT)	
656	3,3'-methylenebis[5-methyloxazolidine] (Oxazolidin / MBO)	



387	N,N'-methylenebismorpholine (MBM)	4,4'-methylenebis-morpholine already in table 1
691	Sodium N-(hydroxymethyl)glycinate	Already in table 1 (CAS no: 70161-44-3)
382	Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione (TMAD)	