

1. Formulation of the criterion

Hazardous substances

According to Article 6(6) of the regulation No 66/2010 on EU Ecolabel, the product or any part of it thereof shall not contain substances or mixtures meeting the criteria for classification with the hazard classes or categories in accordance with Regulation (EC) no 1227/2008 specified below nor shall it contain substances referred to in Article 57 of REACH Regulation (EC) no 1907/2006. The risk phrases below generally refer to substances. However, for mixtures of substances where information on the substances is difficult to obtain, classification for rules of mixtures may be applied. The term mixture and substance are used as defined within the CLP Regulation (EC) No 1272/2008.

Table 1 Risk phrases and Hazard statements

Hazard Statement ¹	Risk Phrase ²
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23; R26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60-63
H360Df May damage the unborn child. Suspected of damaging fertility	R61-62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23; R39/24; R39/25; R39/26; R39/27; R39/28
H371 May cause damage to organs	R68/20; R68/21; R68/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25; R48/24; R48/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20; R48/21; R48/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41

Explanatory note for the criterion on "Hazardous Substances" -1st Proposal for discussion in the 2nd AHWG meeting 24th Sept. 2012 for the EU Ecolabel Criteria for Paints and Varnishes

Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

¹Regulation (EC) no 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no 1907/2006

²Directive 67/548/EEC with adjustment to REACH according to Directive 2006/12/EC and Directive 1999/45/EC as amended.

Derogations: Following substances are exempt from this criterion

Table 2 Following substances are exempt from this criterion

1	2	3	4	5	6	7	8	9	
Derogation number a/a	USE	Chemical Composition Ingredient	CAS nr/ EINECS Nr / REACH registration Nr *	Classification	Requirement	Maximum allowed concentration % w/w	Only for a transition period of 2 years	Type of paint	
1	In can preservative	2-Methyl-2H-isothiazol-3-one	2682-20-4	R 22-23-34-43-50	1, 5, 8, 9	0,1%	X		
2		1,2-Benzisothiazol-3(2H)-one	2634-33-5	R 22-38-41-43-50	1, 5, 8, 9	0,1%	X		
3		Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazol-2,5(1H,3H)-dion	5395-50-6	R43	2, 8, 9	0.080%	X		
4		bronopol (INN) 2-bromo-2-nitropropane-1,3-diol	52-51-7	R21/22 R37/38-41, R50	2, 5, 8, 9	0.100%	X		
5		mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9	R23/24/25-34-43-50-53	2,3, 5, 8, 9	0.002%			
6		Sodium N-(hydroxymethyl)glucinate	70161-44-3	Xi; R36, R43	8, 9	0.050%			
7		3-iodo-2-propinyl-butylcarbamate (IPBC)	55406-53-6 EINECS: 259-627-5	R 20/22-41-50	8, , 9	0,3%			
8		Pyrithione zinc	13463-41-7	R 22-23-38-41-50	2, 5, 8, , 9	0,1%		Outdoor paint – façade coatings	
						0,020%		All paints in film	
9		Dry film preservative	terbutryn	886-50-0	Xn, Xi, N; R 22-43-50/53 Or Xn R22; Xn R48/22; Xi R43; R52/53 Or only R 50/53	2, 5, 8, 9	0.100%		
10			4,5-Dichloro-2-octyl-3(2H)-isothiazolone	64359-81-5	C;R34, Xi;R37, Xi;R43, N;R50	5, 8, 9	0.700%		
11			Pyrithione zinc	13463-41-7	R 22-23-38-41-50	2, 5, 8, 9	0,1%		Outdoor paint – façade coatings
	0,020%						All paints in film		
12	Cobalt, complexes de neodecanoate et de borate		68457-13-6	Xn, N, R38, R43, R50/53, R22	5, 8, 9	0.025%	X		
13	3-iodo-2-propinyl-butylcarbamate (IPBC)		55406-53-6	R 20/22-41-50	2, 8, 5, 9	0,3%			

			EINECS: 259-627-5					
14		2-Octyl-2H-isothiazol-3-one	26530-20-1	R 22, 23/24-34-43-50/53	1, 2, 5, 8, 9	0.040%	X	
15		zinc oxide	1314-13-2	R 50/53	2, 5, 8, 9	2%	X	
16		Sodium polynaphthalene sulphonate	9084-06-4	R 52/53	2, 5, 8, 9	0.1%	X	
17	Neutralising agent-pH corrector	triethylamine	121-44-8	R11 - R22 - R23/24 - R35 - R41	2, 9	0.200%	X	
18		Alkanolamine	102-79-4	Xi: R41	9	2.000%		
19		Ammoniaque	1336-21-6	C, N, R34, R50	5, 9	0.200%		
20		2-amino-2-methylpropanol	124-68-5	Xi: R36/38; R52/53	5, 9	0.200%		
21		Ammonia	7664-41-7	R10; R23; R34; R50	2,5, 9	0.065%	X	
		RTECS #: BO0875000						
22		2,2'-iminodiethanol (DEA)	111-42-2	R22-48/22; R38-41	2, 9	2.000%	X	
23	Cobalt dryer	Cobalt bis(2-ethylhexanoate)	136-52-7	Xi; R43 N; R50/53	2,4,5, 9	1%;	X	
24		Fatty acids, tall-oil, cobalt salts	61789-52-4	Xn; R22 Xi; R43 , N; R51/53	4,5, 9	0.500%	X	
25		Neodecanoic acid	26896-20-8	R52/53	4,5, 9	1.000%	X	
26	Zinc dryer	Hexanoic acid, 2-ethyl-, zinc salt,BASIC	85203-81-2	R38, R51/53	5, 9		X	
27	Anti-skinning agent	2-butanone oxime ethyl methyl ketoxime / ethyl methyl ketone oxime	96-29-7	R40; R21; R41, R43	6, 9	0.400%	X	
28		Acideoctanoique, sel de zirconium	18312-04-4	Xi, R38	9	1.300%	X	
29		lithium neodecanoate	27253-30-1	Xi, R38 Or Xi R38 ; R52/53	5	0.200%	X	
30		Manganese salts	CAS 15956-58-8 or CAS 27253-32-3	Xi;R38.	9	4%		
31		Zirconium salt of 2-ethylhexanoic acid	22464-99-9	Xn, R20	9	0.600%	X	
32	Other driers	Iron(1+), chloro[dimethyl-9,9-dihydroxy-3-methyl-2,4-di-(2-pyridyl-kN)-7-[(2-pyridinyl-kN)methyl]-3,7-diazabicyclo[3.3.1]nonane-1,5-dicarboxylate-kN3, kN7]-, chloride(1-)	478945-46-9	Xn; R22 Xn; R48/22 Xi; R43 R52/53	2, 5	0.050%	X	
33	UV protection filtre (Light stabilizer)	Melange de : bis(2,2,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decanedioate; 1,8-bis((2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-decan-1,10-dioxy)piperidin-1-yl)oxy)octane	406-750-9	R53	5, 9	0.60%	X	Outdoor paints

34		Bumetrizole	3896-11-5	R53	5, 9	1.00%	X	Outdoor paints
35		reaction mass of α -3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl- ω -hydroxypoly(oxyethylene) and α -3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl- ω -3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyloxypoly(oxyethylene)	EC: 400-830-7	R43 R51-53	5, 9	0.990%	X	Outdoor paints
36		bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate 70 - 80 % Xi - N R43 - R50/53	41556-26-7	R43 R50/53	5, 9	0.600%	X	Outdoor paints
37		methyl 1,2,2,6,6-pentamethyl-4-piperidylsebacate	82919-37-7	R43-R50/53	5, 9	0.200%	X	Outdoor paints
38		de 3-(3-(2h-benzotriazol-2-yl)5-(1,1-dimethylethyl)-4-hydroxyphenyl)propionates de c7-c9 alkyleramifie et lineaire	127519-17-9	R51/53	5, 9	0.500%	X	Outdoor paints
39	Anticorrosive pigment (solid corrosive inhibitor).	zinc phosphate (2,5% ZnPO4)	ZnPO4: 7779-90-0	R50/53	5, 9	8-10%	X	
40		Zinc oxide	1314-13-2	R50/53	5, 9	2%	X	
41	Substrate Wetting agent / surface tension modifier	Polypropylene glycol alkylphenyl ether	9064-13-5	R43	9	3.000%	X	
42		Polyoxyethyleneisodecyl ether	61827-42-7	Xi; R41 & Xn; R22	9	2.000%	X	
43		Alcohols, C9-C11, ethoxylated	68439-46-3	Xi; R41	9	2.000%	X	
44		Secondary Alcohols, C11-C15, ethoxylated	68131-40-8	Xi; R38, R41	9	2.000%	X	
45		Secondary Alcohols, C12-C14, ethoxylated	84133-50-6	Xi; R41	9	2.000%	X	
46		Alcohols, C16-C18, ethoxylated	68439-49-6	Xi, N, R50, R41 or Xn R22 ; Xi; R41	5, 9	2.000%	X	
47		Fatty alcohol ethoxylated	None	Xi; R41	9	2.000%	X	
48		Alcohols, tallow,ethoxylated	61791-28-4	Xn; R22 ; Xi; R41	9	2.000%	X	
49		Alcohols, C12-14,ethoxylated	68439-50-9	Xi; R41; N; R50	5, 9	2.000%	X	
50		Polyoxyethylenetriodecyl ether phosphate	9046-01-9	Xi; R38 ; R41	9	2.000%	X	
51		Poly(oxy-1,2-ethanedediyl),a-isotridecyl-w-hydroxy-,phosphate	73038-25-2	Xi; R38 ; R41; R52/53	5, 9	2.000%	X	
52		Polyoxyethylenestearyl ether	9005-00-9	Xi; R41	9	2.000%	X	
53		Isotridecanol, ethoxylated	9043-30-5 69011-36-5	Xn; R22 ; Xi; R41	9	2.000%	X	
54		Alkyl polyglucoside	500-220-1	Xi; R41	9	2.000%	X	
55		Tridecyl(polyethyleneoxy)ethanol	78330-21-9	Xn; R22 ; Xi; R41	9	2.000%	X	
56		Sodium di-(2-ethylhexylic) sulfosuccinate	577-11-7	Xi; R38 ; R41	9	0.200%	X	
57		2,4,7,9-tetramethyldec-5-yne-4,7-diol	126-86-3 / EINECS: 204-809-1	R 36, R 52/53	5, 9	0.25%	X	
58		Alkoxyated Alcohol	None	R52/53	5, 9	2.000%	X	

59	Silicon Resin Emulsion	triethoxy(2,4,4-trimethylpentyl)silane	35435-21-3	R10 ; R52/53	5, 9	3.000%	X	
60	Solvent (in composition of some ingredients)	Hydrocarbures, C10-C13, n-alcanes, isoalcanes, cycliques, < 2% aromatiques	01-2119457273-39-XXXX	Xn; R65, R66	9	2.000%	X	
61		2-methylpropan-1-ol	78-83-1	R10 Xi; R37/38-R41 R67	9	2.000%	X	
62		Petroleum distillates, solvent dewaxed heavy paraffinic (DMSO extract <3%)	64742-65-0	CAS N°64742-65-0 ; 72623-87-1 : These CAS N° stands for a Toxic R45 substance except the DMSO extract is below 3% (Note H,L)	9	2.000%	X	
63		Hydrocarbures en c12-18	93924-45-9	Xn, R65, R66	9	0.060%	X	
64		Ethylene glycol monobutyl ether	111-76-2	Xn; R20/21/22 - Xi; R36/38	9	1%	X	
65		Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based	72623-87-1	CAS N°64742-65-0 ; 72623-87-1 : These CAS N° stands for a Toxic R45 substance except the DMSO extract is below 3% (Note H,L)	9	2.000%	X	
66		Pigment	Nickel Titanium Yellow	8007-18-9	Heavy metal	9	2.000%	X
67		leucophyllite minerals containing crystalline silica classified STOT RE 1 and STOT RE 2		R48/25/24/23 or R48/20/21/22	9, 10	0.500%		All paints
68		crystalline silica classified STOT RE 1 or STOT RE 2 contained in fillers		R48/25/24/23 or R48/20/21/23	9, 10	0.500%		All paints
69		Heptanes (Naphtha),	092045-53-9	R11, 38, 51/53, 65, 67	5, 9	0.020%	X	
70		Complex alkanolamine	068784-47-4	R36/38	9	1.000%	X	
71		Diethylene glycol (EC No. 2038722)	000111-46-6	R22	9	0.500%	X	
72		iso-Propanol	000067-63-0	R11, 36, 67	9	0.020%	X	
73	Unreacted impurity	Volatile Aromatic Hydrocarbons	Various	Various	7			

Notes:

1. The sum of the total allowable concentration of these compounds is 0.05 % (w/w) before or after tinting (if applicable). For outdoor wood coatings the total allowable concentration shall not exceed 0.2 % (w/w).
2. The sum of the total allowable concentration of these compounds is 0.1% w/w).
3. The sum of the total allowable concentration of these compounds is 0.0015 % (w/w).
4. These compounds can only be used in alkyd paints and varnishes and up to a concentration not exceeding 0,05 % (w/w), measured as % of cobalt metal in the end product.
5. Substances or mixtures can have an allowable maximum concentration of 2% (w/ww/w) in the final paint formulation.
6. May be used in alkyd paints up to a limit of 0.3 % (w/w) in the final paint formulation.
7. Ingredients containing VAH may be added up to such a limit that the VAH content in the end product will not exceed 0,1 % (w/w). In this context volatile aromatic hydrocarbon (VAH) means any organic compound, as defined in Directive 2004/42/EC, having an initial boiling point less than or equal to 250 °C measured at a standard pressure of 101,3 kPa and having at least one aromatic nucleus in its developed structural formula.
8. The product may include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. These biocides shall be registered in the Biocide Product Regulation (BPD) scheme. Further, in accordance with Directive 67/548/EEC, Directive 1999/45/EC of the European Parliament and of the Council or Regulation (EC) No 1272/2008 substances or mixtures used as preservatives, that are classified as: H400, H410, H411, H412 and H413 are permitted but only if their bioaccumulation potentials are characterised by log Kow (log octanol/water partition coefficient) < 3,0 or an experimentally

determined bioconcentration factor (BCF) ≤ 100 .

9. After a transition period of two years the paint formulation shall not contain any hazardous substances, or combinations thereof, that result in the formulation being greater than 0.7 of the limits defined within PART A of directive 1999/45/EC and as required by the CLP regulation for marking dangerous substances.
10. Derogation is granted provided that the user before and during the paint use cannot come in contact with the substance in a dry form (e.g. the substance is within the liquid paint).

The final product must not be labelled according to the hazard statements above.

Concentration limits for substances or mixtures which may be or have been assigned the hazard statements or risk phrase listed above, or which meet the criteria for classification in the hazard classes or categories listed in the table above, and concentration limits for substances meeting the criteria set out in Article 57(a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration limits determined in accordance with the Article 10 of Regulation (EC) No 1272/2008. Where specific concentration limits are determined, they shall prevail over the generic ones.

Concentration limits for substances meeting the criteria set out in Article 57(d), (e) or (f) of Regulation (EC) No 1907/2006 shall not exceed 0.1% weight by weight.

Assessment and verification: The applicant shall provide a declaration of compliance with this criterion, together with a product material safety data sheet meeting the requirements of Annex II to the REACH Regulation and the quantity, in % (w/w), for all chemicals where derogations are sought. The applicant shall provide copies of the material safety data sheets of any preservatives added, together with information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product

2. Scope of the criterion

In this criterion all the " substances or mixtures meeting the criteria for classification with the hazard classes" presented in the respective table (list of R-/H-phrases) found in the final product ("the product or any part of it thereof shall not contain") are covered.

The general concentration limit for use is 0.1% ("Concentration limits for substances meeting the criteria set out in Article 57(d), (e) or (f) of Regulation (EC) No 1907/2006 shall not exceed 0.1% weight by weight.") but " Where specific concentration limits are determined, they shall prevail over the generic ones."

3. Derogation Requests

The table 2 presents the derogated substances. Information of table 2 is described in the following.

The substances which are proposed for derogation are sorted per function group indicated in column 2 of Table 2. This means e.g. that the derogation of substances 1 to 8 is based on the fact that they are necessary because they are used as "in can preservatives".

Further, for each substance is given the CAS-Number and its classification with one or more Risk phrases of table 1. These substances would have been banned if no derogation would have been granted because of their Risk phrase classification.

The substances that are listed in table 2 in order to be derogated shall also fulfil additional requirements. These are described in the notes. Which requirement is applicable for each substance is given in column 6 of table 2. Two examples with the requirements given in the notes are presented at the end of this document.

Further, in column 7 of table 2 is presented the maximum allowable concentration. The derogated substances are allowed for use so far their concentration does not exceed the thresholds given.

In column 8 of table 2 are marked substances for which some stakeholders indicated that are not used in their formulations. These substances are currently flagged and are proposed to be allowed for a transition period of 2 years.

Finally, in column 9 of table 2 are indicated for which type of paints the use of the substances is allowed. Unless otherwise indicated the derogation is allowed for all types of paints.

Stakeholders have suggested that there can be cases of specific paint types for which the flagged substances (column 8) are necessary. This implies that the manufacturers who claimed that the use of the flagged substances is not necessary do not produce all type of paints (e.g. refer to indoor wall paints). A further elaboration of column 8 and 9 of table 2 could address this point so far additional information is given. In this case then for specific type of paints a derogation of the flagged substances (of column 8) could be exceptionally valid without time limitations (now it is given a 2 years transition period).

Examples:

-note 8

" The product may include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. These biocides shall be registered in the Biocide Product Regulation (BPD) scheme. Further, in accordance with Directive 67/548/EEC, Directive 1999/45/EC of the European Parliament and of the Council or Regulation (EC) No 1272/2008 substances or mixtures used as preservatives, that are classified as: H400, H410, H411, H412 and H413 are permitted but only if their bioaccumulation potentials are characterised by log Kow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100 . "

This requirement is applicable to the substances used as in can preservatives and dry film preservatives (working in both cases as biocides) (derogations 1-16). As described in the background report the current hazardous substances criterion supersedes a separate requirement on biocides. Biocides are classified with the indicated above risk phrases so they fall under the hazardous substances criterion. The substances which are classified and are used as preservatives shall additionally fulfil the above described requirement

-note 9

"After a transition period of two years the paint formulation shall not contain any hazardous substances, or combinations thereof, that result in the formulation being greater than 0.7 of the limits defined within PART A of directive 1999/45/EC and as required by the CLP regulation for marking dangerous substances."

This requirement is applicable to all the derogated substances. With the current proposal a (relative high) number of substances are derogated. Not all of these substances are used in one product (paint formula). However, in order to prevent that Ecolabelled paint contains in the end a relatively high number of derogated but still hazardous substances this requirement is proposed. In this way the final product is "distanced" from being classified by 30%. Accepting industry request a transition period of 2 years is suggested until this requirement is applied. This was important as the in June 2015 SDS have to be compliant with CLP and in the meanwhile IT systems to calculate the CLP labelling are for many manufacturers not in place.