EUROPEAN
COMMISSION

Brussels, XXX
[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2018/669

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 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[1], and in particular Articles 37(5) and 53(1) thereof,

Whereas:

Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains the list of harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to that Regulation.

(1) Proposals to introduce harmonised classification and labelling of certain substances and to update or delete the harmonised classification and labelling of certain other substances have been submitted to the European Chemicals Agency pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of the Agency (RAC), as well as on the comments received from the parties concerned, it is appropriate to introduce, update, delete or leave unchanged harmonised classification and labelling of certain substances.

(2) It is appropriate and scientifically justified to follow RAC's opinions regarding the hazard classes proposed for the harmonised classification and labelling of certain substances.

(3) Acute Toxicity Estimates (ATE) are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. The inclusion of harmonised ATE values in the entries listed in Annex VI to Regulation (EC) No 1272/2008 facilitate the harmonisation of the classification of mixtures and provide support for enforcement authorities. Following further scientific assessments on some substances, ATE values have been calculated and should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation 1272/2008. The substances concerned are methylmercuric chloride, pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), pentasodium

[1] OJ L 353, 31.12.2008, p.1.

(carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate, ethylene oxide; oxirane and metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane.

(4) In its scientific opinion of 22 September 2017 on the substance cobalt, RAC proposed to classify that substance as carcinogen category 1A with a specific concentration limit of ≥ 0,01 %. However, the methodology used to determine a specific concentration limit required further assessment in particular of its applicability to metal compounds. It is therefore appropriate not to introduce, for the time being, any specific concentration limit in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 for cobalt, in which case the general concentration limit of ≥ 0,1 % should apply, in accordance with Table 3.6.2 of Annex I to that Regulation.

(5) In its scientific opinion of 14 September 2017 on the substance titanium dioxide, RAC proposed to classify that substance as carcinogen category 2 by inhalation. As titanium dioxide induced-lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. In addition, as some dangerous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users on the precautionary measures that need to be taken to minimise the hazard for human health.

(6) Regulation (EC) No 1272/2008 should therefore be amended accordingly.

(7) Commission Regulation (EU) 2018/669[2] provides for the translation of chemical names into all official languages of the Union, except Irish. Regulation (EU) 2018/669 contains the harmonised classification, labelling and packaging for the substance pitch, coal tar, high temp. as applicable on 1 January 2016. However, Commission Regulation (EU) No 944/2013[3] amended the harmonised classification, labelling and packaging of that substance as from 1 April 2016. Due to an administrative oversight, Regulation (EU) 2018/669 did not take into account the amendments introduced with Regulation (EU) No 944/2013. As Regulation (EU) 2018/669 will become applicable as of 1 December 2019, it will erroneously re-introduce the original classification, labelling and packaging for the entry pitch, coal tar, high temp. Regulation (EU) 2018/669 should therefore be corrected accordingly.

(8) To ensure that suppliers of substances and mixtures have time to adapt to the new classification and labelling provisions, the application of this Regulation should be deferred.

(9) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of application of this Regulation.

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[2] Commission Regulation (EU) 2018/669 of 16 April 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 115, 4.5.2018, p. 1).

[3] Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 261, 3.10.2013, p. 5).

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[4],

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

Regulation (EC) No 1272/2008 is amended as follows:

(1) Annex II is amended as set out in Annex I to this Regulation.

(2) Annex III is amended as set out in Annex II to this Regulation.

(3) Annex VI is amended as set out in Annex III to this Regulation.

Article 2

Correction to Regulation (EU) 2018/669

The Annex to Commission Regulation (EU) 2018/669 is corrected as set out in Annex IV to this Regulation.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [OP: please insert date to be determined as follows: Date of entry into force plus 18 months – the date should be the 1st day of the following month.]

Article 2 shall apply from 1 December 2019.

By way of derogation from the second paragraph, substances and mixtures may, before [*OP: **please insert specific date of application determined under the second paragraph***], be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1).

Done at Brussels,

For the Commission
The President
[…]

EN
Annexes 1 to 4

ANNEX I

In Annex II to Regulation (EC) No 1272/2008, in Part 2, the following section 2.12 is inserted:

‘2.12. **Mixtures containing titanium dioxide**.

The label on the packaging of liquid mixtures containing 1% or more of titanium dioxide particles with a diameter equal to or below 10 µm shall bear the following statement:

EUH211: 'Warning! Dangerous droplets may be formed when sprayed. See information supplied by the manufacturer. Comply with the safety instructions.'

The label on the packaging of solid mixtures containing 1% or more of titanium dioxide shall bear the following statement:

EUH212: 'Warning! Dangerous dust may be formed when used. See information supplied by the manufacturer. Comply with the safety instructions.'

The label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous which are labelled with EUH211 or EUH212, shall bear statement EUH210 in addition.

ANNEX II

In Part 3 of Annex III to Regulation (EC) No 1272/2008, in Table 2.1, the following rows EUH 211 and EUH 212 are inserted:

‘EUH211	Language	Warning! Dangerous droplets may be formed when sprayed. See information supplied by the manufacturer. Comply with the safety instructions.
EUH212	Language	Warning! Dangerous dust may be formed when used. See information supplied by the manufacturer. Comply with the safety instructions.’

ANNEX III

Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) Part 1 is amended as follows:

(a) in point 1.1.3.1, the following note V is added:

'Note V:

If the substance is placed on the market as fibres (with diameter < 3 μm, length > 5 μm and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry their hazardous properties must be evaluated in accordance with Title II of Regulation (EC) No 1272/2008 to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.';

(b) in point 1.1.3.2, the following note 10 is added:

'Note 10:

The classification as a carcinogen by inhalation applies only to mixtures placed on the market in powder form containing 1% or more of titanium dioxide particles with diameter ≤ 10 μm.';

(2) in Part 3, Table 3 is amended as follows:

(a) the rows corresponding to index numbers 604-083-00-X and 611-159-00-6 are deleted;

(b) the rows corresponding to index numbers 015-189-00-5, 027-001-00-9, 028-018-00-4, 603-023-00-X, 605-005-00-7, 606-047-00-9, 607-232-00-7, 607-247-00-9, 608-039-00-0, 613-054-00-0, 616-018-00-2 and 648-055-00-5 are replaced by the following rows respectively:

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
‘015-189-00-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	423-340-5	162881-26-7	Skin Sens. 1A Aquatic Chronic 4	H317 H413	GHS07 Wng	H317 H413’			
‘027-001-00-9	cobalt	231-158-0	7440-48-4	Carc. 1B Muta. 2 Repr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4	H350 H341 H360F H334 H317 H413	GHS08 Dgr	H350 H341 H360F H334 H317 H413’			
‘028-018-00-4	nickel bis(sulfamidate); nickel sulfamate	237-396-1	13770-89-3	Carc. 1A Muta. 2 Repr. 1B Acute Tox. 4 STOT RE 1 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D*** H302 H372** H334 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350i H341 H360D*** H302 H372** H334 H317 H410		oral: ATE = 853 mg/kg bw (anhydrate) oral: ATE = 1098 mg/kg bw (tetrahydrate) STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1’	H
‘603-023-00-X	ethylene oxide; oxirane	200-849-9	75-21-8	Flam. Gas 1 Press. Gas Carc. 1B Muta. 1B Repr. 1B Acute Tox. 3 Acute Tox. 3 STOT SE 3 STOT SE 3 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H220 H350 H340 H360Fd H331 H301 H335 H336 H372 (nervous system) H314 H318	GHS02 GHS08 GHS06 GHS05 Dgr	H220 H350 H340 H360Fd H331 H301 H335 H336 H372 (nervous system) H314		inhalation: ATE = 700ppm (gases) oral: ATE = 100 mg/kg bw’	U

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
‘605-005-00-7	metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	Flam. Sol. 2 Repr. 2 Acute Tox. 3 Aquatic Chronic 3	H228 H361f H301 H412	GHS02 GHS08 GHS06 Dgr	H228 H361f H301 H412		oral: ATE = 283 mg/kg bw’	
‘606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS08 GHS09 Dgr	H360D H410’			
‘607-232-00-7	pyridate (ISO); *O*-(6-chloro-3-phenylpyridazin-4-yl) *S*-octyl thiocarbonate	259-686-7	55512-33-9	Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H315 H317 H400 H410	GSH07 GHS09 Wng	H302 H315 H317 H410		oral: ATE = 500 mg/kg bw M=1 M=10’	
‘607-247-00-9	dodecyl methacrylate	205-570-6	142-90-5	STOT SE 3	H335	GHS07 Wng	H335		STOT SE 3; H335: C ≥ 10%’	
‘608-039-00-0	2-phenylhexanenitrile	423-460-8	3508-98-3	Acute Tox. 4 Aquatic Chronic 2	H302 H411	GHS07 GHS09 Wng	H302 H411		oral: ATE = 500 mg/kg bw’	
‘613-054-00-0	thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole	205-725-8	148-79-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1’	
‘616-018-00-2	diethyltoluamide (ISO): *N*,*N*-diethyl-*m*-toluamide; [deet]	205-149-7	134-62-3	Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2	H302 H315 H319	GHS07 Wng	H302 H315 H319		oral: ATE = 1892 mg/kg bw’	

(c) the following rows are inserted:

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
‘022-006-002	titanium dioxide; [in a powder form containing 1% or more of particles with diameter ≤ 10 μm]	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	GHS08 Wng	H351 (inhalation)			V, 10
080-004-00-7	methylmercuric chloride	204-064-2	115-09-3	Carc. 2 Repr. 1A Lact. Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H360Df H362 H330 H310 H300 H372 (nervous system, kidneys) H400 H410	GHS08 GHS06 GHS09 Dgr	H351 H360Df H362 H330 H310 H300 H372 (nervous system, kidneys) H410		inhalation: ATE = 0,05 mg/l (dusts or mists) dermal: ATE = 50 mg/kg bw oral: ATE = 5 mg/kg bw	1
601-090-00-X	benzo[*rst*]pentaphene	205-877-5	189-55-9	Carc. 1B Muta. 2	H350 H341	GHS08 Dgr	H350 H341			
601-091-00-5	dibenzo[*b*,*def*]chrysene; dibenzo[*a*,*h*]pyrene	205-878-0	189-64-0	Carc. 1B Muta. 2	H350 H341	GHS08 Dgr	H350 H341			
603-236-00-8	ethanol, 2,2'-iminobis-, *N*-(C13-15-branched and linear alkyl) derivs.	308-208-6	97925-95-6	Repr. 1B	H360D	GHS08 Dgr	H360D			
607-733-00-0	cyflumetofen (ISO); 2-methoxyethyl (*RS*)-2-(4-*tert*-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-*o*-tolyl)propionate	-	400882-07-7	Carc. 2 Skin Sens. 1A	H351 H317	GHS08 GHS07 Wng	H351 H317			

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-734-00-6	pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D H332 H373 (inhalation) H319	GHS08 GHS07 Dgr	H360D H332 H373 (inhalation) H319		inhalation: ATE = 1,5 mg/l (dusts or mists)	
607-735-00-1	*N*-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D H332 H373 (inhalation) H319	GHS08 GHS07 Dgr	H360D H332 H373 (inhalation) H319		inhalation: ATE = 1,5 mg/l (dusts or mists)	
607-736-00-7	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Repr. 1B Acute Tox. 4 STOT RE 2	H360D H332 H373 (inhalation)	GHS08 GHS07 Dgr	H360D H332 H373 (inhalation)		inhalation: ATE = 1,5 mg/l (dusts or mists)	
607-737-00-2	diisohexyl phthalate	276-090-2	71850-09-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
608-069-00-4	fludioxonil (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	-	131341-86-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=10	
613-329-00-5	halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1*H*-pyrazole-4-carboxylate	-	100784-20-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS08 GHS09 Dgr	H360D H410		M=1000 M=1000	
613-330-00-0	2-methylimidazole	211-765-7	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df			

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
616-225-00-8	(*RS*)-2-methoxy-*N*-methyl-2-[α-(2,5-xylyloxy)-*o*-tolyl]acetamide; mandestrobin	-	173662-97-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=10	
616-226-00-3	carboxin (ISO); 2-methyl-*N*-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide	226-031-1	5234-68-4	STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H373 (kidneys) H317 H400 H410	GHS08 GHS07 GHS09 Wng	H373 (kidneys) H317 H410		 M=1 M=1	
616-227-00-9	metaflumizone (ISO); (*EZ*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-*m*-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [*E*-isomer ≥ 90%, *Z*-isomer ≤10% relative content]; [1] (*E*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2]	-	139968-49-3 [1] 852403-68-0 [2]	Repr. 2 Lact. STOT RE 2	H361fd H362 H373	GHS08 Wng	H361fd H362 H373			
650-056-00-0	dibutylbis(pentane-2,4-dionato-*O*,*O*')tin	245-152-0	22673-19-4	Repr. 1B STOT RE 1	H360FD H372 (immune system)	GHS08 Dgr	H360FD H372 (immune system)'			

ANNEX IV

In the Annex to Commission Regulation (EU) 2018/669, the row with Index No ‘648-055-00-5’ is replaced by the following:

‘648-055-00-5	pitch, coal tar, high-temp.; [The residue from the distillation of high temperature coal tar. A black solid with an approximate softening point from 30 °C to 180 °C (86 °F to 356 °F). Composed primarily of a complex mixture of three or more membered condensed ring aromatic hydrocarbons.]	266-028-2	65996-93-2	Carc. 1A Muta. 1B Repr. 1B	H350 H340 H360FD	GHS08 Dgr	H350 H340 H360FD’			