Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 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 that Regulation (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/217

of 4 October 2019

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 that Regulation

(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:

(1) 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.

(2) 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 ('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 or delete harmonised classification and labelling of certain substances. Those RAC opinions[(2)] are:

— Opinion of 9 June 2017 concerning 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol

— Opinion of 22 September 2017 concerning disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene- 2,7-disulfonate

— Opinion of 9 June 2017 concerning Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide;

— Opinion of 22 September 2017 concerning cobalt;

- Opinion of 22 September 2017 concerning nickel bis(sulfamidate); nickel sulfamate;
- Opinion of 22 September 2017 concerning ethylene oxide; oxirane;
- Opinion of 22 September 2017 concerning 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane; metaldehyde;
- Opinion of 15 March 2017 concerning 2-benzyl-2-dimethylamino-4'morpholinobutyrophenone;
- Opinion of 5 December 2017 concerning pyridate (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate;
- Opinion of 22 September 2017 concerning dodecyl methacrylate;
- Opinion of 5 December 2017 concerning 2-phenylhexanenitrile;
- Opinion of 15 March 2017 concerning thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole;
- Opinion of 9 June 2017 concerning N,N-diethyl-m-toluamide; deet;
- Opinion of 14 September 2017 concerning Titanium dioxide;
- Opinion of 15 March 2017 concerning Methylmercuric chloride;
- Opinion of 9 June 2017 concerning benzo[*rst*]pentaphene;
- Opinion of 9 June 2017 concerning Dibenzo[*b,def*]chrysene; Dibenzo[a,h]pyrene;
- Opinion of 22 September 2017 concerning Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs;
- Opinion of 5 December 2017 concerning cyflumetofen (ISO); 2-methoxyethyl (RS) -2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-o-tolyl)propionate;
- Opinion of 9 June 2017 concerning Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate;
- Opinion of 9 June 2017 concerning N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid);
- Opinion of 9 June 2017 concerning pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo) tetraacetate;
- Opinion of 9 June 2017 concerning diisohexyl phthalate;
- Opinion of 9 June 2017 concerning fludioxonil (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile;
- Opinion of 22 September 2017 concerning halosulfuron-methyl (ISO); methyl 3-chloro-5{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole4-carboxylate;
- Opinion of 5 December 2017 concerning 2-methylimidazole;
- Opinion of 15 March 2017 concerning (RS)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-o-tolyl]acetamide; mandestrobin;
- Opinion of 5 December 2017 concerning carboxin (ISO); 2-methyl-N-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide;

— Opinion of 5 December 2017 concerning 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];

— Opinion of 5 December 2017 concerning Dibutylbis(pentane-2,4-dionato-O,O')tin.

(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 facilitates the harmonisation of the classification of mixtures and provides support for enforcement authorities. Following further scientific assessments of some substances, ATE values have been calculated for methylmercuric chloride, pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), ethylene oxide, oxirane and metaldehyde (ISO), 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane, in addition to those proposed in the RAC opinions. Those ATE values should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(4) In its scientific opinion of 22 September 2017 on the substance cobalt, RAC proposed to classify that substance as carcinogen category 1B 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 % applies, 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, retention and poor solubility of the particles in the lung, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. The deposited particles, but not solutes of titanium dioxide, are assumed to be responsible for the observed toxicity in the lung and subsequent tumour development. In order to avoid unjustified classification of non-hazardous forms of the substance, specific notes should be laid down for the classification and labelling of the substance and mixtures containing it. In addition, as some hazardous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users of the precautionary measures that need to be taken to minimise the hazard for human health.

(6) With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)

and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), the classification as acute toxicant category 4 and specific target organ toxicant - repeated exposure (category 2) recommended in the RAC opinions of 9 June 2017 should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate and N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), the classification as eye irritant category 2, recommended in the RAC opinions of 9 June 2017, should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. However, the classification of the substances pentapotassium 2,2',2'',2''',2'''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), as toxic for reproduction category 1B should not be included, since it requires further assessment by RAC in view of new scientific data on toxicity for reproduction presented by the industry after the RAC opinions were forwarded to the Commission.

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

(8) Regulation (EC) No 1272/2008 contains the harmonised classification, labelling and packaging for the substance pitch, coal tar, high temp. The Commission amended the harmonised classification, labelling and packaging of that substance by Commission Regulation (EU) No 944/2013[(3)] with effect from 1 April 2016. Commission Regulation (EU) 2018/669[(4)] further amended Regulation (EC) No 1272/2008. However, due to an administrative oversight, certain amendments – the validity of which was not affected by the judgment of the General Court in Case T-689/13[(5)] as upheld by the judgment of the Court of Justice in Case C-691/15 P[(6)] – introduced by Regulation (EU) No 944/2013 were not reflected in Regulation (EU) 2018/669. That Regulation will become applicable as of 1 December 2019. Regulation (EC) No 1272/2008 should therefore be corrected, with effect from the same date.

(9) 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.

(10) In order to be consistent with the approach underpinning Article 61(2) of Regulation (EC) No 1272/2008, suppliers should have the possibility of applying the classification, labelling and packaging provisions introduced by this Regulation on a voluntary basis before its date of application,

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 (EC) No 1272/2008

Annex VI to Regulation (EC) No 1272/2008 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 9 September 2021.

However, Article 2 shall apply from 1 December 2019.

Substances and mixtures may, before 9 September 2021, 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.

Done at Brussels, 4 October 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I

Part 2 of Annex II to Regulation (EC) No 1272/2008 is amended as follows:

(1) The introductory paragraph is amended as follows:

> The statements set out in sections 2.1 to 2.10 and 2.12 shall be assigned to mixtures in accordance with Article 25(6).

(2) Section 2.12 is added:

2.12. **Mixtures containing titanium dioxide**

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

EUH211: 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.'

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

EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

In addition, 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.

ANNEX II

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

EUH211	**Language**	
	BG	Внимание! При пулверизация могат да се образуват опасни респирабилни капки. Не вдишвайте пулверизираната струя или мъгла.
	ES	¡Atención! Al rociar pueden formarse gotas respirables peligrosas. No respirar el aerosol.
	CS	Pozor! Při postřiku se mohou vytvářet nebezpečné respirabilní kapičky. Nevdechujte aerosoly nebo mlhu.

	DA	Advarsel! Der kan danne sig farlige respirable dråber, når der sprayes. Undgå indånding af spray eller tåge.
	DE	Achtung! Beim Sprühen können gefährliche lungengängige Tröpfchen entstehen. Aerosol oder Nebel nicht einatmen.
	ET	Hoiatus! Pihustamisel võivad tekkida ohtlikud sissehingatavad piisad. Pihustatud ainet või udu mitte sisse hingata.
	EL	Προσοχή! Κατά τον ψεκασμό μπορούν να σχηματιστούν επικίνδυνα εισπνεύσιμα σταγονίδια. Μην αναπνέετε το εκνέφωμα ή τα σταγονίδια.
	EN	Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.
	FR	Attention! Des gouttelettes respirables dangereuses peuvent se former lors de la pulvérisation. Ne pas respirer les aérosols ni les brouillards.
	GA	Aire! D'fhéadfaí braoiníní guaiseacha inanálaithe a chruthú nuair a spraeáiltear an táirge seo. Ná hanálaigh sprae ná ceo.
	HR	Upozorenje! Pri prskanju mogu nastati opasne respirabilne kapljice. Ne udisati aerosol ni maglicu.
	IT	Attenzione! In caso di vaporizzazione possono formarsi goccioline respirabili pericolose. Non respirare i vapori o le nebbie.
	LV	Uzmanību! Izsmidzinot var veidoties bīstami ieelpojami pilieni. Ne smidzinājumu, ne miglu neieelpot.

	LT	Atsargiai! Purškiant gali susidaryti pavojingų įkvepiamų lašelių. Neįkvėpti rūko ar aerozolio.
	HU	Figyelem! Permetezés közben veszélyes, belélegezhető cseppek képződhetnek. A permetet vagy a ködöt nem szabad belélegezni.
	MT	Twissija! Jista' jifforma qtar perikoluż li jinġibed man-nifs meta tisprejja minn dan. Tiġbidx l-isprej jew l-irxiex man-nifs.
	NL	Let op! Bij verneveling kunnen gevaarlijke inhaleerbare druppels worden gevormd. Spuitnevel niet inademen.
	PL	Uwaga! W przypadku rozpylania mogą się tworzyć niebezpieczne respirabilne kropelki. Nie wdychać rozpylonej cieczy lub mgły.
	PT	Atenção! Podem formar-se gotículas inaláveis perigosas ao pulverizar. Não respirar a pulverização ou névoas.
	RO	Avertizare! Se pot forma picături respirabile periculoase la pulverizare. Nu respirați prin pulverizare sau ceață.
	SK	Pozor! Pri rozprašovaní sa môžu vytvárať nebezpečné respirabilné kvapôčky. Nevdychujte aerosóly ani hmlu.
	SL	Pozor! Pri razprševanju lahko nastanejo nevarne vdihljive kapljice. Ne vdihavajte razpršila ali meglic.
	FI	Varoitus! Vaarallisia keuhkorakkuloihin kulkeutuvia pisaroita saattaa muodostua suihkutuksen

		yhteydessä. Älä hengitä suihketta tai sumua.
	SV	Varning! Farliga respirabla droppar kan bildas vid sprejning. Inandas inte sprej eller dimma.

EUH212	**Language**	
	BG	Внимание! При употреба може да се образува опасен респирабилен прах. Не вдишвайте праха.
	ES	¡Atención! Al utilizarse, puede formarse polvo respirable peligroso. No respirar el polvo.
	CS	Pozor! Při použití se může vytvářet nebezpečný respirabilní prach. Nevdechujte prach.
	DA	Advarsel! Der kan danne sig farligt respirabelt støv ved anvendelsen. Undgå indånding af støv.
	DE	Achtung! Bei der Verwendung kann gefährlicher lungengängiger Staub entstehen. Staub nicht einatmen.
	ET	Hoiatus! Kasutamisel võib tekkida ohtlik sissehingatav tolm. Tolmu mitte sisse hingata.
	EL	Προσοχή! Κατά τη χρήση μπορεί να σχηματιστεί επικίνδυνη εισπνεύσιμη σκόνη. Μην αναπνέετε τη σκόνη.
	EN	Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.
	FR	Attention! Une poussière respirable dangereuse peut se former lors de l’utilisation. Ne pas respirer cette poussière.

	GA	Aire! D'fhéadfaí deannach guaiseach inanálaithe a chruthú nuair a úsáidtear an táirge seo. Ná hanálaigh deannach.
	HR	Upozorenje! Pri prskanju može nastati opasna respirabilna prašina. Ne udisati prašinu.
	IT	Attenzione! In caso di utilizzo possono formarsi polveri respirabili pericolose. Non respirare le polveri.
	LV	Uzmanību! Izmantojot var veidoties bīstami ieelpojami putekļi. Putekļus neieelpot.
	LT	Atsargiai! Naudojant gali susidaryti pavojingų įkvepiamų dulkių. Neįkvėpti dulkių.
	HU	Figyelem! Használatkor veszélyes, belélegezhető por képződhet. A port nem szabad belélegezni.
	MT	Twissija! Meta jintuża dan, jista' jifforma trab perikoluż li jinġibed man-nifs. Tiġbidx it-trab man-nifs.
	NL	Let op! Bij gebruik kunnen gevaarlijke inhaleerbare stofdeeltjes worden gevormd. Stof niet inademen.
	PL	Uwaga! W przypadku stosowania może się tworzyć niebezpieczny pył respirabilny. Nie wdychać pyłu.
	PT	Atenção! Podem formar-se poeiras inaláveis perigosas ao pulverizar. Não respirar as poeiras.
	RO	Avertizare! Se poate forma pulbere respirabilă periculoasă în timpul utilizării. Nu inspirați pulberea.

	SK	Pozor! Pri použití sa môže vytvárať nebezpečný respirabilný prach. Nevdychujte prach.
	SL	Pozor! Pri uporabi lahko nastane nevaren vdihljiv prah. Prahu ne vdihavajte.
	FI	Varoitus! Vaarallista keuhkorakkuloihin kulkeutuvaa pölyä saattaa muodostua käytön yhteydessä. Älä hengitä pölyä.
	SV	Varning! Farligt respirabelt damm kan bildas vid användning. Inandas inte damm.

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 notes V and W are added:
Note V:

If the substance is to be 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 this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.
Note W:

‘It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung.

This note aims to describe the particular toxicity of the substance; it does not constitute a criterion for classification according to this Regulation.’;

(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 in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 μm.;

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

(a) the rows with 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 dichloride	231-589-4	7646-79-9	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	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;	

				Aquatic Chronic 1					H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M = 1’
‘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’
‘605-005-00-7	Tebuconazole (ISO);	403-640-2	107534-96-3	Flam. Sol. 2	H228 H361f H301 H412	GHS02 GHS08 GHS06 Dgr	H228 H361f H301 H412		oral: ATE = 283

	2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane			Repr. 2 Acute Tox. 3 Aquatic Chronic 3					mg/kg bw’	
‘606-047-00-9	4-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’			
‘607-232-00-2	pyridaben (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate	259-685-7	96489-71-3	Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H315 H317 H400 H410	GHS07 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 %’	
‘608-029-00-0	4-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’	
‘613-054-00-7	thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole	205-725-8	148-79-8	Aquatic Acute 1 Aquatic	H400 H410	GHS09 Wng	H410		M = 1 M = 1’	

				Chronic 1						
‘616-018-00-1	diethyltoluamide (ISO): N,N-diethyl-m-toluamide; [deet]	205-149-1	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)		
‘022-006-00-2	titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 μm]	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	GHS08 Wng	H351 (inhalation)			V, W, 10’
‘080-012-00-1	dimethylbenzethonium chloride	204-064-3	91-09-3	Carc. 2 Repr. 1A Lact. Acute Tox. 2 Acute Tox. 2	H351 H360D H362 H330 H310 H300 H372 (nervous system, kidneys)	GHS08 GHS06 GHS09 Dgr	H351 H360Df H362 H330 H310 H300 H372 (nervous system, kidneys)		inhalation: ATE = 0,05 mg/l (dusts or mists) dermal: ATE	1’

				Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H400 H410		H410		= 50 mg/ kg bw oral: ATE = 5 mg/ kg bw	
‘601-090-00-X	benzo[*a*]pyrene	200-028-5	50-32-8	Muta. 1B Repr. 1B	H340 H360FD	GHS08 Dgr	H340 H360FD’			
‘601-091-00-5	dibenzo[*a*,*h*]anthracene; dibenzo[*a*,*h*]pyrene	200-181-8	53-70-3	Carc. 1B Muta. 2	H350 H341	GHS08 Dgr	H350 H341’			
‘603-237-00-8	ethanol, 2,2’-iminobis-, *N*-(C13-15-branched and linear alkyl) derivs.	308-208-8	97925-85-6	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’			
‘607-734-00-6	pentapotassium 2,2’,2’’,2’’’,2’’’’-(ethane-1,2-diylnitrilo)pentaacetate	240-290-7	7216-95-7	Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H332 H373 (inhalation) H319	GHS08 GHS07 Dgr	H332 H373 (inhalation) H319		inhalation: ATE = 1,5 mg/l (dusts or mists)’	
‘607-735-00-1	carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Acute Tox. 4	H332 H373 (inhalation)	GHS08 GHS07 Dgr	H332 H373 (inhalation)		inhalation: ATE = 1,5	

				STOT RE 2 Eye Irrit. 2	H319		H319		mg/l (dusts or mists)’
‘607-736-00-3	pentasodium (carboxylatomethyl)inos	205-391-3	150-01-4	Acute Tox. 4 STOT RE 2	H332 H373 (inhalation)	GHS08 GHS07 Dgr	H332 H373 (inhalation)		inhalation: ATE = 1,5 mg/l (dusts or mists)’
‘607-737-00-9	di-n-hexyl phthalate	201-559-5	84-75-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD’		
‘608-069-00-4	fluoxastrobin (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-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	foramsulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-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	211-766-3	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df		
‘616-228-00-8	(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’
‘616-229-00-3	carboxin (ISO);	226-035-1	5234-68-4	STOT RE 2	H373 (kidneys)	GHS08 GHS07	H373 (kidneys)		M = 1

	2-methyl-N-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide			Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS09 Wng	H317 H410		M = 1’	
‘616-227-00-9	2-methylimizone (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’			
‘650-058-00-4	bis(4-methylbenzene-1,2-diolato-O,O’)tin	56-00-4 [1] 52263-32-9 [2]		Repr. 1B	H360FD	GHS08 Dgr	H360FD			

				STOT RE 1	H372 (immune system)		H372 (immune system)’.			

ANNEX IV

In Annex VI to Regulation (EC) No 1272/2008, in table 3, the row with Index No ‘648-055-00-5’ is replaced by the following:

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)		
‘648-055-00-5	Residues (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	266-028-2	65996-93-2	Carc. 1A Muta. 1B Repr. 1B	H350 H340 H360FD	GHS08 Dgr	H350 H340 H360FD’.			

	three or more membered condensed ring aromatic hydrocarbons.]									

(**1**) OJ L 353, 31.12.2008, p. 1.

(**2**) https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/name/-/ecNumber/-/casNumber/-/dte_receiptFrom/-/dte_receiptTo/-/prc_public_status/Opinion+Adopted/dte_withdrawnFrom/-/dte_withdrawnTo/-/sbm_expected_submissionFrom/-/sbm_expected_submissionTo/-/dte_finalise_deadlineFrom/-/dte_finalise_deadlineTo/-/haz_addional_hazard/-/lec_submitter/-/dte_assessmentFrom/-/dte_assessmentTo/-/prc_regulatory_programme/-/

(**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).

(**4**) 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).

(**5**) Judgment of the General Court of 7 October 2015, *Bilbaína de Alquitranes and Others v Commission*, T-689/13, EU:T:2015:767.

(**6**) Judgment of the Court of 22 November 2017, *Commission v Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/217.