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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)

(OJ L 44, 18.2.2020, p. 1)

Corrected by:

►**C1** Corrigendum, OJ L 51, 25.2.2020, p. 13 (2020/217)
►**C2** Corrigendum, OJ L 214, 17.6.2021, p. 72 (2020/217)

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COMMISSION DELEGATED REGULATION (EU) 2020/217

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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)

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.

▼C1

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 1 October 2021.

However, Article 2 shall apply from 1 December 2019.

Substances and mixtures may, before 1 October 2021, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

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

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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.’

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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.

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‘EUH211	Language	
	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.

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‘EUH212	Language	
	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 inspiraţi 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.’

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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:

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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’	
‘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

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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	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 %’	
‘608-039-00-0	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’	

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(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)		
'►C2 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'
'080-012-00-0	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'			

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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)		
‘607-733-00-0	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	404-290-3	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	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	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)’	
‘607-736-00-7	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Acute Tox. 4 STOT RE 2	H332 H373 (inhalation)	GHS08 GHS07 Dgr	H332 H373 (inhalation)		inhalation: ATE = 1,5 mg/l (dusts or mists)’	
‘607-737-00-2	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)-1H-pyrrole-3-carbonitrile	—	131341-86-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10’	

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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)		
‘613-329-00-5	halosulfuron-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	211-765-7	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df			
‘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’	

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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)		
‘616-227-00-9	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)’.			

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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	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'.			