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

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. |

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| | | |
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| | DA | Advarsel! Der kan danne sig farlige respirable dråber, når der sprayeres. 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 inánálaithe 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. |

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| | | |
|--|----|--|
| | 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' jiffirma 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. Sputnevel 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 |

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| | | |
|---------------|-----------------|---|
| | | 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. |

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| | | |
|--|----|---|
| | GA | Aire! D'fhéadfaí deannach guaiseach inánálaithe 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' jiforma trab perikoluż li jingibed 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. |

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| | | |
|--|----|---|
| | SK | Pozor! Pri použití sa môže vytvárat' 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;

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- (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 Code(s) | Hazard Signal Code(s) | Hazard statement Code(s) | Suppl. Hazard statement Code(s) | | |
| '015-189-00-5 | bis(2,4,6-trimethylbenzoyl)-phosphine oxide | 4123-3406 | 288 | Sens. 1A Aquatic Chronic 4 | H317 H413 | GHS07 Wng | H317 H413 | | | | |
| '027-001-00-9 | | 231-1574 | 40-48 | Ac. 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 | bis(sulfamidate); nickel sulfamate | 4237-3963 | 770-893 | 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; | | |

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| | | | | | | | | |
|--------------------------------|--|--|--|--|--|---|---|--|
| | | | | Aquatic Chronic 1 | | | | H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M = 1' |
| '603-021-00-200-8495921- X | ethylene oxide; oxirane | | | 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 H360F 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' |
| '605-005-00-20346008-621- X | methoxy (ISO); 2,4,6,8- tetramethyl- tetraoxacyclooctane | | | Flam. Sol. 2 Repr. 2 | H228 H361f H301 H412 | GHS02 GHS08 GHS06 Dgr | H228 H361f H301 H412 | oral: ATE = 283 mg/ |

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| | | | | | | | | |
|-------------------------|---|--|--|---|--------------------------------------|-----------------------|------------------------------|--|
| | | | | Acute Tox. 3 Aquatic Chronic 3 | | | | kg bw' |
| '606-027-00-904-3601931 | benzyl-2-dimethylamino-4'-morpholinobutyroph... | | | Rep1 1B Aquatic Acute 1 Aquatic Chronic 1 | H360D H400 H410 | GHS08 GHS09 Dgr | H360D H410 | |
| '607-237-00-259-6855712 | (ISO); O- (6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate | | | 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' |
| '607-247-00-205-5704690 | methacrylate | | | STOT SE 3 | H335 | GHS07 Wng | H335 | STOT SE 3; H335: C ≥ 10 %' |
| '608-029-00-023-4635898 | phenylhexanenitrile | | | Acute Tox. 4 Aquatic Chronic 2 | H302 H411 | GHS07 GHS09 Wng | H302 H411 | oral: ATE = 500 mg/ kg bw' |
| '613-054-00-025-7254879 | (ISO); 2- (thiazol-4-yl)benzimidazole | | | Aquatic Acute 1 Aquatic Chronic 1 | H400 H410 | GHS09 Wng | H410 | M = 1 M = 1' |
| '616-018-00-205-493462 | (ISO); N,N- | | | Acute Tox. 4 | H302 H315 H319 | GHS07 Wng | H302 H315 H319 | oral: ATE = |

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|--|--|--|--|---|--|--|--|--|-----------------------|
| | diethyl- m- toluamide; [deet] | | | Skin Irrit. 2 Eye Irrit. 2 | | | | | 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 Code(s) | Hazard Signal word | Hazard statement Code(s) | | |
| '022-006-0022 | dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] | 2236-67534 | 63-67-7 | Carc. 2 | H351 (inhalation) | GHS08 | H351 (inhalation) | | | V, W, 10' |
| '080-012-0010 | chloride | 204-06443 | 13-09-02 | Carc. 2 Repr. 1A Lact. Acute Tox. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 | H351 H360Df H362 H330 H310 H300 H372 (nervous system, kidneys) H400 H410 | GHS08 GHS09 GHS09 | 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 | |

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| | | | | Aquatic Chronic 1 | | | | | |
| '601-090-00-205-87785-559-X | 09-00-205-87785-559 | 2,2,4,4-tetraphenylpropane | 400882-07-7 | Carc. Muta. 2 | H350 H341 | GHS08 Dgr | H350 H341 | | |
| '601-091-00-205-87780-640 | 09-00-205-87780-640 | dibenzo[<i>a,h</i>]pyrene | 400882-07-7 | Carc. Muta. 2 | H350 H341 | GHS08 Dgr | H350 H341 | | |
| '603-226-00-208-2087025-156 | 226-00-208-2087025-156 | 2,2'-iminobis-, <i>N</i> -(C13-15- branched and linear alkyl) derivs. | 400882-07-7 | Repr. 1B | H360D | GHS08 Dgr | H360D | | |
| '607-734-00-200-6567843-0 | 734-00-200-6567843-0 | tofen 400882-07-7 (ISO); 2- methoxyethyl (<i>RS</i>)-2- (4- <i>tert</i> - butylphenyl)-2- cyano-3- oxo-3- (α,α,α - trifluoro- <i>o</i> - tolyl)propionate | 400882-07-7 | Carc. 2 Skin Sens. 1A | H351 H317 | GHS08 GHS07 Wng | H351 H317 | | |
| '607-734-00-200-6567843-0 | 734-00-200-6567843-0 | 2,2',2'',2''',2''''- (ethane-1,2- diyl)nitro)pentaacetate | 400882-07-7 | Acute Tox. 4 STOT RE 2 Eye Irrit. 2 | H332 H373 H319 | GHS08 GHS07 Dgn (inhalation) H319 | H332 H373 (inhalation) H319 | | inhalation: ATE = 1,5 mg/ l (dusts or mists)? |
| '607-735-00-200-6567843-0 | 735-00-200-6567843-0 | carboxymethylimino bis(ethylene glycol) (acetic acid) | 400882-07-7 | Acute Tox. 4 STOT RE 2 Eye Irrit. 2 | H332 H373 H319 | GHS08 GHS07 Dgn (inhalation) H319 | H332 H373 (inhalation) H319 | | inhalation: ATE = 1,5 mg/ l (dusts or mists)? |

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|-----------------------------|---|------------|--|-------------------------------|-----------------------|--------------------------|--|
| '607-736-00-205-39149-01 | (carboxylatomethyl)ironobis(ethyltetraacetate) | 149-01 | Acute H332 (inhalation) STOT RE 2 | H332 (inhalation) | GHS08 (Dgr) | H332 (inhalation) | inhalation: STE = 1,5 mg/l (dusts or mists)' |
| '607-737-00-276-0901250-094 | phthalate | 1250-094 | Repr. 1B | H360FD | GHS08 (Dgr) | H360FD' | |
| '608-069-00-401-13134 | (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile | 13134 | Acute H410 Aquatic Chronic 1 | Acute H410 Aquatic Chronic 1 | GHS09 (Wng) | H410 | M = 1 M = 10' |
| '613-329-00-549-100784201 | methyl (ISO); methyl 3-chloro-5-[[4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate | 100784201 | Repr. 1B Aquatic Acute 1 Aquatic Chronic 1 | H360D H400 H410 | GHS08 (Dgr) | H360D H410 | M = 1000 M = 1000' |
| 613-330-00-0211-76693-98 | methylimidazole | 6693-98 | Repr. 1B | H360D | GHS08 (Dgr) | H360Df | |
| '616-228-00-28-1736629701 | methoxy-N-methyl-2-[α-(2,5-xylyloxy)-o-tolyl]acetamide; mandestrobin | 1736629701 | Acute H410 Aquatic Chronic 1 | Acute H410 Aquatic Chronic 1 | GHS09 (Wng) | H410 | M = 1 M = 10' |
| '616-226-00-326-035234-6810 | (ISO); 2-methyl-N-phenyl-5,6- | 35234-6810 | STOT RE 2 Skin Sens. 1 | H373 (kidneys) H317 H400 H410 | GHS08 (G) GHS09 (Wng) | H373 (kidneys) H317 H410 | M = 1 M = 1' |

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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 Notes Conc. Limits, M-factors and ATEs |
|----------------|---|-----------|--------|-----------------------------------|--------------------------|--------------|------------------------|--------------------------|---|
| | | | | Hazard Class and Category Code(s) | Hazard statement Code(s) | Pictogram | Signal Word Code(s) | Hazard statement Code(s) | |
| '648-055-00-5' | 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 | 266-028-6 | 5996-9 | Carc. 1B Muta. 1B Repr. 1B | H350 H340 H360FD | GHS08 Dgr | H350 H340 H360FD | | |

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| aromatic hydrocarbons.] | | | | | | | | |
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Changes to legislation:

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