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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 3 February 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.: C(2021) 441 final - C(2021) 441 final ANNEX

Subject: ANNEX to the Commission Delegated Regulation (EU) ../. of XXX amending for the purposes of its adaptation to technical and scientific progress, Part 1 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Delegations will find attached document C(2021) 441 final - C(2021) 441 final ANNEX.

Encl.: C(2021) 441 final - C(2021) 441 final ANNEX



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ANNEX

ANNEX

to the

Commission Delegated Regulation (EU) ../.

**of XXX amending for the purposes of its adaptation to technical and scientific progress,
Part 1 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of
the Council on classification, labelling and packaging of substances and mixtures**

ANNEX

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

(1) in point 1.1.3.1., notes J to R are replaced by the following:

‘Note J:

The harmonised classification as a carcinogen or mutagen applies unless it can be shown that the substance contains less than 0,1 % w/w benzene (EINECS No 200-753-7), in which case a classification in accordance with Title II of this Regulation shall be performed also for those hazard classes.

Note K:

The harmonised classification as a carcinogen or mutagen applies unless it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (EINECS No 203-450-8), in which case a classification in accordance with Title II of this Regulation shall be performed also for those hazard classes. Where the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (P102-)P210-P403 shall apply.

Note L:

The harmonised classification as a carcinogen applies unless it can be shown that the substance contains less than 3 % of dimethyl sulphoxide extract as measured by IP 346 (‘Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions - Dimethyl sulphoxide extraction refractive index method’ Institute of Petroleum, London), in which case a classification in accordance with Title II of this Regulation shall be performed also for that hazard class.

Note M:

The harmonised classification as a carcinogen applies unless it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (EINECS No 200-028-5), in which case a classification in accordance with Title II of this Regulation shall be performed also for that hazard class.

Note N:

The harmonised classification as a carcinogen applies unless the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen, in which case a classification in accordance with Title II of this Regulation shall be performed also for that hazard class.

Note P:

The harmonised classification as a carcinogen or mutagen applies unless it can be shown that the substance contains less than 0,1 % w/w benzene (EINECS No 200-753-7), in which case a classification in accordance with Title II of this Regulation shall be performed also for those hazard classes. Where the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (P102-)P260-P262-P301 + P310-P331 shall apply.

Note Q:

The harmonised classification as a carcinogen applies unless one of the following conditions is fulfilled:

- a short term biopersistence test by inhalation has shown that fibres longer than 20 µm have a weighted half-life less than 10 days; or
- a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 µm have a weighted half-life less than 40 days; or
- an appropriate intra-peritoneal test has provided no evidence of excess carcinogenicity; or
- no relevant pathogenicity or neoplastic changes are noted in a suitable long term inhalation test

Note R:

The harmonised classification as a carcinogen applies except in the case of fibres with a Length Weighted Geometric Mean Diameter (LWGMD) minus two geometric standard errors greater than 6 µm, as measured in accordance with Test method A.22 in the Annex to Commission Regulation (EC) No 440/2008*.

* Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

(2) in point 1.1.3.2., Notes 8 and 9 are replaced by the following:

‘N o t e 8:

The classification as a carcinogen shall apply unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 0,1 %.

N o t e 9 :

The classification as a mutagen shall apply unless it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 1 %.’