



EUROPEAN
COMMISSION

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ANNEX

ANNEX

to the

Commission Delegated Regulation (EU)

**amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council
as regards the addition of notes**

ANNEX

Part 1 of Annex VI to Regulation (EC) No 1272/2008 is amended as follows:

(1) in Section 1.1.3.1, the following Notes Y and Z are added:

‘Note Y:

The harmonised classification as persistent, bioaccumulative and toxic (PBT) applies unless it can be shown that the substance contains less than 0,1 % w/w octamethylcyclotetrasiloxane; [D4] (EC Number: 209-136-7), in which case an assessment for a classification as PBT in accordance with Title II of this Regulation shall be performed.

Note Z:

Entries bearing this Note have a name referring to a group of substances. Where the supplier can provide the name of a specific substance in line with Note A, Article 18(2) applies to this more precise identification. Therefore, the supplier shall select a corresponding identification number, where available.’;

(2) in Section 1.1.3.2, the following notes 14, 15, 16, 17, 18, 19, 20 and 21 are added:

‘Note 14:

The classification of mixtures as endocrine disruptors for human health is necessary if the sum of the concentrations of individual substances covered by this entry in the mixture as placed on the market is equal to, or above: (i) the applicable generic concentration limit for the assigned hazard class and category code, or (ii) a specific concentration limit given in this entry.

Note 15:

The classification of mixtures as endocrine disruptors for the environment is necessary if the sum of the concentrations of individual substances covered by this entry in the mixture as placed on the market is equal to, or above: (i) the applicable generic concentration limit for the assigned hazard class and category code, or (ii) a specific concentration limit given in this entry.

Note 16:

The classification of mixtures as PBT is necessary if the sum of the concentrations of individual substances covered by this entry in the mixture as placed on the market is $\geq 0,1$ %.

Note 17:

The classification of mixtures as very persistent and very bioaccumulative (vPvB) is necessary if the sum of the concentrations of individual substances covered by this entry in the mixture as placed on the market is $\geq 0,1$ %.

Note 18:

The classification of mixtures as PBT or vPvB is necessary if the sum of the concentrations in the mixture as placed on the market of individual substances to which this Note is assigned is equal to, or above, the applicable generic concentration limit for PBT or vPvB.

Note 19:

The classification of mixtures as endocrine disruptors for the environment is necessary if the sum of branched and linear, ethoxylated 4-nonylphenols, i.e. para-isomers, whatever their molecular weight, is equal to, or above, the applicable generic concentration limit for endocrine disruptors for the environment.

Note 20:

The classification of mixtures as endocrine disruptors for human health or for the environment is necessary if the sum of the concentrations in the mixture as placed on the market of individual substances to which this Note is assigned is equal to, or above, the applicable generic concentration limit for endocrine disruptors for human health or for the environment.

Note 21:

The classification of mixtures as vPvB is necessary if the sum of the concentrations in the mixture as placed on the market of individual substances to which this Note is assigned is equal to, or above, the applicable generic concentration limit for vPvB.’.

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