



Council of the
European Union

Brussels, 11 January 2024
(OR. en)

5359/24
ADD 1

ENT 11
CHIMIE 7
MI 33
COMPET 44
IND 24
SAN 22
ENV 45

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	8 January 2024
To:	General Secretariat of the Council
No. Cion doc.:	[...] (2023) XXX draft - D 090609/3 ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6)

Delegations will find attached document [\[...\]](#)(2023) XXX draft - D 090609/3 ANNEX.

Encl.: [\[...\]](#)(2023) XXX draft - D 090609/3 ANNEX



EUROPEAN
COMMISSION

Brussels, XXX
D090609/03
[...] (2023) XXX draft

ANNEX

ANNEX

to the

**COMMISSION REGULATION (EU) .../...
of XXX**

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament
and of the Council concerning the Registration, Evaluation, Authorisation and
Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane (D4),
decamethylcyclopentasiloxane (D5) and
dodecamethylcyclohexasiloxane (D6)**

ANNEX

Entry 70 of Annex XVII to Regulation (EC) No 1907/2006 is replaced by the following:

<p>‘70.</p> <p>Octamethylcyclotetrasiloxane (D4)</p> <p>CAS No 556-67-2 EC No 209-136-7</p> <p>Decamethylcyclopentasiloxane (D5)</p> <p>CAS No 541-02-6 EC No 208-764-9</p> <p>Dodecamethylcyclohexasiloxane (D6)</p> <p>CAS No 540-97-6 EC No 208-762-8</p>	<ol style="list-style-type: none">1. Shall not be placed on the market<ol style="list-style-type: none">(a) as a substance on its own,(b) as a constituent of other substances, or(c) in mixturesin a concentration equal or greater than 0,1 % by weight of the respective substance after <i>[OP, please insert the date: 2 years after the entry into force of this amending Regulation]</i>.2. Shall not be used as a solvent for the dry cleaning of textiles, leather and fur after <i>[OP, please insert the date: 2 years after the entry into force of this amending Regulation]</i>.3. By way of derogation:<ol style="list-style-type: none">(a) for D4 and D5 in wash-off cosmetic products, paragraph 1, point (c), shall apply after 31 January 2020.<p>For the purposes of this point, ‘wash-off cosmetic products’ means cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*) that, under normal conditions of use, are washed off with water after application;</p>(b) for all cosmetic products other than the ones mentioned in paragraph 3(a), paragraph 1 shall apply after <i>[OP, please insert the date: 3 years after the entry into force of this amending Regulation]</i>;(c) for devices as defined in Article 1 (4) of Regulation (EU) 2017/745 of the European Parliament and of the Council (**) and in Article 1 (2) of Regulation (EU) 2017/746 of the
--	---

	<p>European Parliament and the Council (**), paragraph 1 shall apply after [OP, please insert the date: 7 years after the entry into force of this amending Regulation];</p> <p>(d) for medicinal products, as defined in Article 1, point 2, of Directive 2001/83/EC, and for veterinary medicinal products, as defined in Article 4(1) of Regulation (EU) 2019/6(***), paragraph 1 shall apply after [OP, please insert the date: 7 years after the entry into force of this amending Regulation];</p> <p>(e) for D5 as a solvent in the dry cleaning of textiles, leather and fur, paragraphs 1 and 2 shall apply after [OP, please insert the date: 10 years after the entry into force of this amending Regulation].</p> <p>4. By way of derogation, paragraph 1 shall not apply to the:</p> <p>(a) placing on the market of D4, D5 and D6 for the following industrial uses:</p> <ul style="list-style-type: none"> – as a monomer in the production of silicone polymer; – as an intermediate in the production of other silicone substances; – as a monomer in polymerisation; – in the formulation or (re)packing of mixtures; – in the production of articles; – in non-metal surface treatment; <p>(b) placing on the market of D5 and D6 for use as devices, as defined in Article 1(4) of Regulation (EU) 2017/745, for the treatment and care of scars and wounds, the prevention of wounds and the care of stoma;</p> <p>(c) placing on the market of D5 for professional use in the cleaning or restoration of art and antiques.</p>
--	--

	<p>(d) placing on the market of D4, D5 and D6 for use as laboratory reagent in research and development activities carried out under controlled conditions.</p> <p>5. By way of derogation, paragraph 1, point (b), shall not apply to the placing on the market of D4, D5 and D6:</p> <p>1. as a constituent of a silicone polymer on its own;</p> <p>2. as a constituent of a silicone polymer in a mixture derogated under paragraph 6.</p> <p>3. By way of derogation, paragraph 1, point (c), shall not apply to the placing on the market of mixtures that contain D4, D5 or D6 as residues from silicone polymers, under the following conditions:</p> <p>(a) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in adhesion, sealing, gluing and casting;</p> <p>(b) D4 in a concentration equal to or less than 0,5 % by weight, or D5 or D6 in a concentration equal to or less than 0,3 % by weight of either substance in the mixture for use as protective coatings (including marine coatings);</p> <p>(c) D4, D5 or D6 in a concentration equal to or less than 0,2 % by weight of the respective substance in the mixture, for use as devices as defined in Article 1 (4) of Regulation (EU) 2017/745 and in Article 1 (2) of Regulation (EU) 2017/746, other than the devices referred to in paragraph 6(d);</p> <p>(d) D5 in a concentration equal to or less than 0,3% by weight in the mixture or D6 in a concentration equal to or less than 1 % by weight in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745, for dental impression;</p> <p>(e) D4 in a concentration equal to or less than 0,2 % by weight in the mixture,</p>
--	---

	<p>or D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture for use as silicone insoles for horses, or as horseshoes;</p> <p>(f) D4, D5 or D6 in a concentration equal to or less than 0,5 % by weight of the respective substance in the mixture, for use as adhesion promoters;</p> <p>(g) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in 3D-printing;</p> <p>(h) D5 in a concentration equal to or less than 1 % by weight in the mixture or D6 in a concentration equal to or less than 3 % by weight in the mixture, for rapid prototyping and mould making, or high performance uses stabilised by quartz filler;</p> <p>(i) D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture, for use in pad printing, or manufacturing of printing pads;</p> <p>(j) D6 in a concentration equal to or less than 1 % by weight of the mixture, for professional use in the cleaning or restoration of art and antiques.</p> <p>4. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for use, or to the use, of D5 as a solvent in strictly controlled closed dry cleaning systems for textile, leather and fur, where the cleaning solvent is recycled or incinerated.</p> <p>(*) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59).</p> <p>(**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).</p> <p>(***) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on <i>in vitro</i> diagnostic medical devices and repealing Directive 98/79/EC and</p>
--	---

	<p>Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).</p> <p>(****) Regulation 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ, L 004, 7.1.2019, p. 43).'</p>
--	---