



Brussels, 15 May 2025
(OR. en)

8980/25
ADD 1

ENV 342
ENT 68
COMPET 370
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COVER NOTE

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

date of receipt: 15 May 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: C(2025) 2887 final - Annex

Subject: ANNEX to the COMMISSION DELEGATED REGULATION (EU).../ ... amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards dechlorane plus

Delegations will find attached document C(2025) 2887 final - Annex.

Encl.: C(2025) 2887 final - Annex

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EUROPEAN
COMMISSION

Brussels, 15.5.2025
C(2025) 2887 final

ANNEX

ANNEX

to the

Commission Delegated Regulation (EU).../ ...

**amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as
regards dechlorane plus**

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ANNEX

In Part A of Annex I, the following entry is added:

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
'Dechlorane plus 'Dechlorane plus' includes its syn-isomer and anti-isomer	13560-89-9 135821-03-3 135821-74-8	236-948-9	<p>1. For the purposes of this entry, Article 4(1), point (b), shall apply to concentrations of dechlorane plus:</p> <p>(a) equal to or below 1000 mg/kg (0,1 % by weight) where they are present in substances, mixtures or articles until [OP <i>please insert date</i>: 30 months after entry into force of this Regulation]</p> <p>(b) equal to or below 1 mg/kg (0,0001 % by weight) where they are present in substances, mixtures or articles after [OP <i>please insert date</i>: 30 months after the entry into force of this Regulation].</p> <p>2. By way of derogation, the placing on the market and use of dechlorane plus shall be allowed for the following purposes:</p> <p>(a) aerospace, space and defence applications, until [OP <i>please insert date</i>: 5 years after the entry into force of this Regulation];</p> <p>(b) medical imaging applications, until [OP <i>please insert date</i>: 5 years after the entry into force of this Regulation];</p> <p>(c) radiotherapy devices and installations, until [OP <i>please insert date</i>: 5 years after the entry into force of this Regulation];</p> <p>(d) spare parts for, and the repair</p>

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		<p>of, any of the following:</p> <ul style="list-style-type: none"> (i) land-based motor vehicles; (ii) stationary industrial machines for use in agriculture, forestry and construction; (iii) marine, garden, forestry and outdoor power equipment other than that covered under (ii); (iv) aerospace, space and defence applications; (v) instruments for analysis, measurements, control, monitoring, testing, production and inspection; <p>where dechlorane plus was initially used in their production, until the end of their service life or until 31 December 2043, whichever comes earlier.</p> <p>(e) spare parts for, and the repair of, any of the following:</p> <ul style="list-style-type: none"> (i) medical devices and accessories for medical devices within the scope of Regulation (EU) 2017/745; (ii) in-vitro diagnostic medical devices and accessories for in-vitro diagnostic medical devices within the scope of Regulation (EU) 2017/746; <p>where dechlorane plus was initially used in their production, until the end of their service life.</p> <p>3. The Commission shall assess the need for a prolongation of the specific exemptions in points (a), (b) and (c) of paragraph 2 at the</p>
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			<p>latest by 1 April 2028.</p> <p>4. Articles containing dechlorane plus already in use in the Union before or on the date of expiry of the relevant exemption laid down in paragraph 2(a) to (d) may continue to be used.</p> <p>5. Placing on the market and use of spare parts containing dechlorane plus referred to in paragraph 2, point (d)(iv) that are present in the territory of the Union before or on 31 December 2043 shall be allowed.</p>
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