



Brussels, **XXX**
[...](2025) **XXX** draft

ANNEX

ANNEX

to the

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

**amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as
regards medium chain chlorinated paraffins**

ANNEX

In Part A of Annex I to Regulation (EU) 2019/1021, the following entry is added:

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
<p>'Medium-chain chlorinated paraffins (MCCPs)</p> <p>'Medium-chain chlorinated paraffins' or 'MCCPs' means the following:</p> <p>Substances or mixtures that contain any of the following linear C₁₄₋₁₇ chloroalkanes of the following molecular formulae:</p> <p>C₁₄H_(30-y)Cl_y where y ≥ 5; C₁₅H_(32-y)Cl_y where y ≥ 5; C₁₆H_(34-y)Cl_y where y ≥ 6; C₁₇H_(36-y)Cl_y where y ≥ 6.</p>	<p>[1] 85535-85-9 [2] 198840-65-2 [3] 1372804-76-6 and others</p>	<p>[1] 287-477-0 [2] - [3] - and others</p>	<p>1. For the purposes of this entry, Article 4(1), point (b), shall apply to the sum of concentrations of the linear C₁₄₋₁₇ chloroalkanes of the following molecular formulae:</p> <p>C₁₄H_(30-y)Cl_y where y ≥ 5; C₁₅H_(32-y)Cl_y where y ≥ 5; C₁₆H_(34-y)Cl_y where y ≥ 6; C₁₇H_(36-y)Cl_y where y ≥ 6 equal to or below 1000 mg/kg (0,1 % by weight) where they are present in substances, mixtures or articles.</p> <p>2. By way of derogation, the manufacturing, placing on the market and use of MCCPs shall be allowed for the following purposes:</p> <p>(a) extreme pressure additive in metalworking fluids which are used in professional or industrial settings in 'heavy-duty' metal working operations and for which collection systems are in place, until 31 December 2036;</p> <p>(b) polymers and rubbers which are used in spare parts for, and in the repair of, any of the following:</p> <ul style="list-style-type: none"> (i) land-based motor vehicles; (ii) machinery used in agriculture;

			<p>construction, forestry or landscaping;</p> <p>(iii) electric and electronic equipment for medical devices within the scope of Regulation (EU) 2017/745;</p> <p>(iv) electric and electronic equipment for in-vitro diagnostic devices within the scope of Regulation (EU) 2017/746;</p> <p>(v) instruments for measurement, analysis, manufacturing, control, monitoring, testing and inspection</p> <p>(vi) aerospace and defence applications;</p> <p>where MCCPs were initially used in their production, until the end of their service life or until 31 December 2041, whichever comes earlier;</p> <p>(c) flexible polyvinyl chloride in wires and cables in medical devices within the scope of Regulation (EU) 2017/745 and in-vitro diagnostic devices within the scope of Regulation (EU) 2017/746, until ... [OP, please insert the date: 5 years after the date of entry into force of the amendment to Annex A];</p> <p>(d) adhesives, sealants and tape used for non-structural bonding for aerospace and defence applications, until ... [OP: please insert the date = 5 years after the date of entry into force of the amendment to Annex A];</p> <p>(e) Paints and coatings for</p>
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		<p>ammunition and ammunition markings, until ... [OP: please insert the date = 5 years after the date of entry into force of the amendment to Annex A];</p> <p>(f) ammunition pyrotechnic defence devices to achieve specific effects, until 31 December 2041;</p> <p>(g) intumescent coating and paint for space and defence equipment and its packaging to protect against extreme temperature, until 31 December 2041;</p> <p>(h) coating and paint for the repair of, and use in replacement spare parts for, space and defence equipment where MCCPs were initially used in the production of that equipment, until the end of service life of the equipment.</p> <p>3. Releases of MCCPs to the environment shall be avoided during manufacture and industrial and professional use of MCCP covered by an exemption set out in point 2 and, if not possible, reduced to as low a level as possible. Exposure to workers shall be minimised.</p> <p>4. Articles containing MCCPs already in use in the Union before or on the date of expiry of the relevant exemption laid down in paragraph 2(b) to (g) may continue to be used.</p> <p>5. Placing on the market and use of spare parts containing</p>
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		<p>MCCPs referred to in paragraph 2, points (b) and (h) that are present in the territory of the Union before 1 January 2042 shall be allowed.</p> <p>6. Manufacturers, suppliers and importers of chlorinated paraffins placing on the market substances or mixtures containing chloroalkanes referred to in point 1 shall provide their downstream users and customers, in the Safety Data Sheet referred to in Article 31 of Regulation (EU) 1907/2006, information on:</p> <p>(i) the sum of the concentrations of the chloroalkanes listed in paragraph 1, if present;</p> <p>(ii) when the sum referred to in point (i) is above 0,1% w/w, the appropriate risk management measures and operating conditions to minimise the releases and exposure.</p> <p>7. Manufacturers, suppliers and importers of chlorinated paraffins shall determine the sum referred to in point 6(i) using representative batches of chlorinated paraffins manufactured in accordance with the same technical specifications by the same manufacturer. The level shall be determined using validated analytical methods. A description of the analytical methods used, and the results</p>
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			obtained to derive the sum referred to in point 6(i) shall be provided to the competent authorities upon their request.’.
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