EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10634/2020 ANNEX
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ANNEX.docx)
[…](2020) XXX draft

ANNEX

ANNEX

to the

Commission Implementing Regulation (EU) .../...

approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4

ANNEX

<table>
<tr><th>Common Name</th><th>IUPAC Name
Identification Numbers</th><th>Minimum degree of purity of the active substance[1]</th><th>Date of approval</th><th>Expiry date of approval</th><th>Product type</th><th>Specific conditions</th></tr>
<tr><td rowspan="3">Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)</td><td rowspan="3">IUPAC name:
Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)

EC No: 201-186-8 and 450-280-7

CAS No: 79-21-0 and 33734-57-5</td><td rowspan="3">The minimum purity of the active substance is not relevant as the active substance is a double equilibrium using hydrogen peroxide, acetic acid and octanoic acid as starting materials. The specifications correspond to a range of concentration.
<table><tr><th colspan="2">Components</th><th>Specifications range content (%w/w)</th></tr><tr><td>Active substance</td><td>Peracetic acid</td><td>1,8 – 13,9</td></tr><tr><td>Active substance</td><td>Peroxyoctanoic acid</td><td>0,15 – 2,42</td></tr><tr><td>Relevant impurity</td><td>Hydrogn peroxyde</td><td>1,1 – 25,45</td></tr><tr><td>Relevant impurity</td><td>Acetic acid</td><td>5,74 - 51</td></tr><tr><td>Relevant impurity</td><td>Octanoic acid</td><td>1,63 – 9,03</td></tr></table></td><td rowspan="3">1 April 2022</td><td rowspan="3">31 March 2032</td><td>2</td><td>The authorisations of biocidal products are subject to the following conditions:
(a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance.
(b) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.</td></tr>
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<tr><td>4</td><td>The authorisations of biocidal products are subject to the following conditions:
(a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for</td></tr>
</table>

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

						authorisation, but not addressed in the Union level assessment of the active substance. (b) Products containing reaction mass of peracetic acid and peroxyoctanoic acid shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[2], unless the Commission has established specific limits on the migration of reaction mass of peracetic acid and peroxyoctanoic acid into food or it has established] in accordance with that Regulation that such limits are not necessary. (c) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.

[2] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).