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From:	European Commission
date of receipt:	30 July 2021
To:	General Secretariat of the Council
No. Cion doc.:	D074174/03 ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion in the Union list of flavourings of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid

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Delegations will find attached document D074174/03 ANNEX.

Encl.: D074174/03 ANNEX



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/10140/2019 Rev. 1 ANNEX  
(POOL/E2/2019/10140/10140R1-EN  
ANNEX.docx) D074174/03  
**[...]**(2021) **XXX** draft

ANNEX

**ANNEX**

**to the**

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

**amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion in the Union list of flavourings of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid**

# ANNEX

In Part A, Section 2, Table 1 of Annex I to Regulation (EC) No 1334/2008, the following entry concerning FL No. 16.130 is inserted after entry 16.127:

16.130	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid	1359963-68-0	2204		At least 99% minimum assay (IR NMR MS)	<p>Note: Part A, Section 2, Note 1 of Annex I to Regulation (EC) No 1334/2008 does not apply to this substance.</p> <p>Restrictions for use as a flavouring substance expressed as a sum of the carboxylic acid and the hemisulfate monohydrate salt, expressed as the acid:</p> <p>In category 1.4. – not more than 10 mg/kg.  In category 1.6.3. – not more than 30 mg/kg.  In category 1.8. – not more than 30 mg/kg.  In categories 2.2.1. and 2.2.2. – not more than 30 mg/kg.  In category 3. – not more than 30 mg/kg.  In category 4.2.3. – not more than 10 mg/kg.  In category 4.2.4.1. –</p>	EFSA
	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid hemisulfate monohydrate salt	1460210-04-1	2204.1		<p>Synonym: 3-quinolinecarboxylic acid, 4-amino-5-[2,2-dimethyl-3-[(1-methylethyl)amino]-3-oxopropoxy]-2-methyl-, sulfate, hydrate (2:1:2).</p> <p>At least 99% minimum assay (HPLC).</p>		

						<p>not more than 30 mg/kg.</p> <p>In category 4.2.4.2. – not more than 10 mg/kg.</p> <p>In categories 4.2.5.1., 4.2.5.2., 4.2.5.3. and 4.2.5.4. – not more than 30 mg/kg.</p> <p>In categories 5.1. and 5.2. – not more than 30 mg/kg.</p> <p>In category 5.3. – not more than 300 mg/kg.</p> <p>In category 5.4. – not more than 30 mg/kg.</p> <p>In category 6.3. – not more than 45 mg/kg.</p> <p>In category 7.2. – not more than 15 mg/kg.</p> <p>In categories 8.3.1, 8.3.2. and 8.3.3. – not more than 15 mg/kg.</p> <p>In categories 8.3.4.1., 8.3.4.2. and 8.3.4.3. – not more than 15 mg/kg.</p> <p>In category 11.2. – not more than 30 mg/kg.</p> <p>In category 12.4. – not more than 30 mg/kg.</p> <p>In category 12.5. – not more than 10 mg/l.</p> <p>In categories 14.1.2., 14.1.3. and 14.1.4. – not more than 7 mg/l.</p>		
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						<p>In categories 14.1.5.1. and 14.1.5.2. – not more than 7 mg/kg.</p> <p>In category 14.2.1. – not more than 7 mg/l.</p> <p>In categories 14.2.2. and 14.2.5. – not more than 10 mg/l.</p> <p>In category 15.1. – not more than 30 mg/kg.</p> <p>In category 16 (excluding products covered in categories 1, 3 and 5) – not more than 15 mg/kg.</p>		
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