



Brussels, **XXX**
SANTE/10140/2019 ANNEX CIS
[...](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 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 of Annex I to Regulation (EC) No 1334/2008 the following entry concerning FL No: 16.130 is added:

"

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)	Restrictions for use as a flavouring substance expressed as a sum of the carboxylic acid and the hemisulfate monohydrate salt, expressed as the acid:	EFSA
	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid hemisulfate monohydrate salt	1460210-04-1	2204.1		Synonym: 3-quinolinecarboxylic acid, 4-amino-5-[2,2-dimethyl-3-[(1-methylethyl)amino]-3-oxopropoxy]-2-methyl-, sulfate, hydrate (2:1:2). At least 99% minimum assay (HPLC).	<p>In category 1.4 – not more than 10 mg/kg</p> <p>In category 1.6.3.– not more than 30 mg/kg</p> <p>In category 1.8. – not more than 30 mg/kg</p> <p>In categories 2.2.1. and 2.2.2 – not more than 30 mg/kg</p> <p>In category 3. – not more than 30 mg/kg</p> <p>In category 4.2.3.– not more than 10 mg/kg</p> <p>In category 4.2.4.1.- 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</p>	

						<p>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> <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.</p>		
--	--	--	--	--	--	---	--	--

						<p>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> <p>Note: Other salts of this acid different than the hemisulfate monohydrate salt are not authorised. Note 1 of section 2 of part A of the annex I to Regulation (EC) No. 1334/2008 does not apply to this acid.</p>		
--	--	--	--	--	--	--	--	--

"