



Brussels, **XXX**  
SANTE/11793/2016 Rev. 1 ANNEX  
(POOL/E2/2016/11793/11793R1-EN  
ANNEX.docx) D073140/03  
[...](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 of 3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1H-pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione in the Union list of flavouring substances**

**ANNEX**

In Annex I, Part A, Section 2, Table 1 to Regulation (EC) No 1334/2008 the following entry concerning FL No 16.127 is inserted, after entry 16.126:

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16.127	3-(1-((3,5-dimethylisoxazol-4-yl)methyl)-1 <i>H</i> -pyrazol-4-yl)-1-(3-hydroxybenzyl)imidazolidine-2,4-dione	1119831-25-2	2161		at least 99%, assay (HPLC/UV)	Restrictions of use as a flavouring substance:  In category 1.4, – not more than 4 mg/kg In category 1.8, – not more than 8 mg/kg In category 3 – not more than 4 mg/kg In category 5.1. – not more than 15 mg/kg In category 5.2. – not more than 16 mg/kg In category 5.3. – not more than 30 mg/kg In category 5.4 – not more than 15 mg/kg In category 6.3. – not more than 25 mg/kg In category 12.1. – not more than 75 mg/kg In category 12.2. – not more than 100 mg/kg In category 12.3. – not more than 25 mg/kg In category 12.4. – not more than 25 mg/kg In category 12.5. – not more than 4 mg/kg	EFSA
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						<p>In category 13.2. – not more than 4 mg/kg</p> <p>In category 13.3. – not more than 4 mg/kg</p> <p>In category 14.1.4 – not more than 4 mg/l (for dairy based drinks only)</p> <p>In category 14.1.5. – not more than 8 mg/kg</p> <p>In category 15.1. – not more than 20 mg/kg</p> <p>In category 16. – not more than 4 mg/l (for dairy based deserts only)</p>		
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