

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

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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:

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:]	EFSA
					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	
					In category 13.2. – not	

		more than 4 mg/kg	
		In category 13.3, – not	
		more than 4 mg/kg	
		In category 14.1.4 – not	
		more than 4 mg/l (for	
		dairy drinks based	
		only)	
		In category 14.1.5. –	
		not more than 8 mg/kg	
		In category 15.1. – not	
		more than 20 mg/kg	
		In category 16. – not	
		more than 4 mg/l (for	
		dairy based deserts	
		only)	

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