ANNEX

Identifica \tiom e	Additiv	e Compo	si tipa çies	Maxim	umMinimu	ııMaxim	u 10 ther	End
number of the		chemica	alor	age	content	content	provisio	nsf
of the holder			a, categor	y	mg/kg o	of		period
additive of		descrip			complet	te		of
authori	sation	analytic	ca a nimal		feed wit	th		authorisation
		method	ļ .		a moist	ure		
					content	of 12		
					%			

Category: nutritional additives. Functional group: amino acids, their salts and analogues.

3c381	L- Additive All	1.	26
	isoleucin <i>compositi</i> amimal		Gotobei me
	Powder species		2030
	with a		be
	minimum		placed
	content		on
	of L-		the
	isoleucine		market
	of 93,4		and
	% (on		used
	a dry		as
	matter		an
	basis)		additive
			consisting
	Characterisation		of
	of the		a
	active		preparation
	substance	2.	În
	L-		the
	isoleucine		directions
	produced		for
	by		use
	fermentation		of
	with		the
	Escherichia		additive
	coli		and
	FERM		premixture
	ABP-10641		the
	IUPAC		storage
	name:		conditions
	(2S,3S)-2-		the
	amino-3-		stability
	methylpentanoic		to
	acid		heat

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

Chemic	al			treatment
formula				and
C6H131				in
CAS				water
number				shall
73-32-5				be
	_			indicated.
Analytic	cal		3.	The
method	a		3.	additive
For the				
identific	cation			may be
of L-				used
isoleuci	ne			
in the				via
feed				water
additive	<u>.</u>			for
	Food			drinking.
	Chemical		4.	Declaration
	Codex			to
	'L-			be
	isoleucine			made
	monograph'			on
For the	monograph			the
quantifi	action			label
	cation			of
of				the
isoleuci	ne			additive
in the				and
feed				premixture:
additive				— 'The
	ion			supplementation
	exchange			with
	chromatography			L-
	coupled			isoleucine,
	with			in
	post-			particular
	column			via
	derivatisation			water
	and			for
	optical			drinking,
	detection			shall
	(IEC-			take
	VIS/			into
	FLD)			account
	or			all
	ion			essential
	exchange			and
	chromatography			and
 	, , , , , , ,	,	<u> </u>	<u> </u>

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

coupled with post-column derivatisation and photometric detection (IEC-VIS) For the quantification of isoleucine in premixtures: — ion-	5.	conditionally essential amino acids in order to avoid imbalances.' — L- isoleucine content. The endotoxin content of the
exchange chromatography coupled with post- column derivatisation and optical detection (IEC- VIS/ FLD) or		additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600
ion exchange chromatography coupled with post- column derivatisation and photometric detection (IEC- VIS) Regulation (EC)	6.	IU endotoxins/ m³ air c. For users of the additive and premixture, feed business operators shall

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b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

For the quantification of isoleucing in compoun feed and feed materials	e d : ion exchange	e.		establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated
	coupled with post-column derivatis and photome detection (IEC-VIS) – Regulati (EC) No 152/2009 (Annex III, F)	ation tric		or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal
quantification of isoleucine water:				protective equipment.

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

		post- column derivatisation and photometric detection (IEC- VIS)		
3c383	L-isoleucin	Additive All acompositionimal Powder species with a minimum content of L- isoleucine of 90 % Characterisation of the active substance L- isoleucine produced by fermentation with Corynebacterium glutamicum KCCM 80189 IUPAC name: (2S,3S)-2- amino-3- methylpentanoic acid Chemical formula: C6H13NO2 CAS number: 73-32-5 Analytical method ^a	2.	26 Gotebeine 2020 be placed on the market and used as an additive consisting of a preparation. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and in water

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

For the				shall
identific	eation			be
of L-				indicated.
isoleuci			3.	The
	ne		3.	
in the				additive
feed				may
additive				be
	Food			used
	Chemical			via
	Codex			water
	'L-			for
	isoleucine			drinking.
			4.	Declaration
F - 11 41 -	monograph'		4.	
For the				to
quantifi	cation			be
of				made
isoleuci	ne			on
in the				the
feed				label
additive				of
	ion			the
	exchange			additive
	chromatography			and
	coupled			premixture:
	with			— 'The
	post-			supplementation
	column			with
	derivatisation			L-
	and			isoleucine,
	optical			in
	detection			particular
	(IEC-			via
	VIS/			water
	FLD)			for
	1 1			
	or			drinking,
	ion			shall
	exchange			take
	chromatography			into
	coupled			account
	with			all
	post-			essential
	column			and
	derivatisation			conditionally
	and			essential
	photometric			amino
	detection			acids
	detection			acids
· · · · · · · · · · · · · · · · · · ·	i I	1	1	112

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

	(IEC-VIS) For the quantification of isoleucine in premixtures: — ion-exchange chromatography	order to avoid imbalances.' L- isoleucine content.
	coupled with post- column derivatisation and optical detection (IEC- VIS/ FLD) or ion	
	exchange chromatography coupled with post- column derivatisation and photometric detection (IEC- VIS) - Regulation (EC) No 152/2009	
	(Annex III, F) For the quantification of	

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

1			I	ı	İ	
	isoleucin	ie				
	in					
	compour	nd				
	feed					
	and					
	feed					
	materials	s:				
	_	ion				
		exchange				
		chromatography				
		coupled				
		with				
		post-				
		column				
		derivatisation				
		and				
		photometric				
		detection				
		(IEC-				
		VIS)				
		_				
		Regulation				
		(EC)				
		No				
		152/2009				
		(Annex				
		III,				
	Ean tha	F)				
	For the	ation				
	quantific	ation				
	of					
	isoleucin	ie				
	in					
	water:					
	_	ion				
		exchange				
		chromatography				
		coupled				
		with				
		post-				
		column				
		derivatisation				
		and				
		photometric				
		detection				

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

		(IEC- VIS)			
Category: S	Sensory additiv	es. Functional gro	up: Flavouring	compounds	
3c381	L-isoleucin	Additive All ecompositionimal Powder with a minimum content of L-isoleucine of 93,4 % (on a dry matter basis) Characterisation of the active substance L-isoleucine) produced by fermentation with Escherichia coli FERM ABP-10641 IUPAC name: (2S,3S)-2-amino-3-methylpentanoic acid Chemical formula: C6H13NO2 CAS number: 73-32-5 Analytical method*		2.	26 Gotobeine 2030 be placed on the market and used as an additive consisting of a preparation The additive shall be incorporate into the feed in the form of a premixture In the directions for use of the additive and premixture the storage

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

For the					conditions
identific	ation				and
of L-					the
isoleucir	le l				stability
in the					to
feed					heat
additive					treatment
	Food				shall
	Chemical				be
	Codex	-			indicated.
	'L-			4.	On On
	isoleucine	۵.		''	the
	monograp				label
For the	monograp				of
quantific	ation				the
of					additive
isoleucir	he				the
in the					following
feed					shall
additive:					be
_	ion				indicated:
	exchange				'Recommended
	chromato				maximum
	coupled				content
	with				of
	post-				the
	column				active
	derivatisa	ition			substance
	and				of
	optical				complete
	detection				feedingstuff
	(IEC-				with
	VIS/				a
	FLD)				moisture
	or				content
_	ion				of
	exchange				12
	chromato	graphy			%:
	coupled				25
	with				mg/
	post-			_	kg.'
	column	,.		5.	The
	derivatisa	ition			functional
	and				group,
	photomet				the
	detection				identification
					number,

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

				i		
		(IEC-				the
		VIS)				name
	For the	,				and
	quantific	ation				the
	of					added
1	isoleucin	e				amount
1	in	C				of
		****				the
	premixtu					
	_	ion-				active
		exchange				substance
		chromate	ography			shall
		coupled				be
		with				indicated
		post-				on
		column				the
		derivatis	ation			label
		and				of
		optical				the
		detection	1			premixtures,
		(IEC-				if
		VIS/				the
		FLD)				following
		or				content
		ion				of
		exchange				the
		chromate	ography			active
		coupled				substance
		with				in
		post-				complete
		column				feedingstuff
		derivatis	ation			with
		and				a
		photome	tric			moisture
		detection				content
		(IEC-				of
		VIS)				12
		_ ′				%
		Regulati	on			is
		(EC)				exceeded:
		No No				25
		152/2009) D			mg/
		(Annex				kg.
					6.	The
		III,			υ.	
		F))				endotoxin
						content
						of
						the

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

					additive
					and
					its
					dusting
					potential
					shall
					ensure
					a
					maximal
					endotoxin
					exposure
					of
					1
					600
					IU
					endotoxins/
					m^3
					air ^c .
				7.	For
					users
					of
					the
					additive
					and
					premixture,
					feed
					business
					operators
					shall
					establish
					operational
					procedures
					and
					organisational
					measures
					to
					address
					potential
					by
					inhalation.
					Where
					those
					risks
					cannot
					be
					eliminated
		1			Cillinated

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

				or
				reduced
				to
				a
				minimum
				by
				such
				procedures
				and
				measures,
				the
				additive
				and
				premixture
				shall
				be
				used
				with
				personal
				protective
				equipment.

a Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1397, ANNEX.