



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/12606/2019 ANNEX  
(POOL/E2/2019/12606/12606-EN  
ANNEX.docx)  
[...] (2020) **XXX** draft

ANNEXES 1 to 2

**ANNEXES**

**to the**

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

**amending Annexes II and III to Regulation (EC) No 1333/2008 of the European  
Parliament and of the Council and the Annex to Commission Regulation (EU)  
No 231/2012 as regards Annatto, Bixin, Norbixin (E 160b)**

## ANNEX I

(1) Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(a) in point 2 of Part A, point 5 is replaced by the following:

'The colours E 123, E 127, E 160b(i), E 160b(ii), E 161g, E 173 and E 180 and mixtures thereof may not be sold directly to the consumer.'

(b) in Part B, point 1: 'Colours', the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following two entries:

E 160b(i)	Annatto bixin
E 160b(ii)	Annatto norbixin

(c) Part E is amended as follows:

1) Category 01.4 (Flavoured fermented milk products including heat-treated products) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	4	(94)	

(ii) the following footnote (94) is added after footnote (74):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

2) Category 01.7.2 (Ripened cheese) is amended as follows:

(i) the entries for E 160b (Annatto, Bixin, Norbixin) are replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	only ripened orange, yellow and broken-white cheese and red and green pesto cheese
	E 160b(ii)	Annatto norbixin	15	(94)	only ripened orange, yellow and broken-white cheese and red and green pesto cheese
	E 160b(ii)	Annatto norbixin	50		only <i>red Leicester</i> cheese
	E 160b(ii)	Annatto norbixin	35		only Mimolette cheese

(ii) the following footnote (94) is added after footnote (83):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

3) Category 01.7.3 (Edible cheese rind) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (67):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

4) Category 01.7.5 (Processed cheese) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	8	(94)	

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

5) in Category 01.7.6 (Cheese products (excluding products falling in category 16)), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	8		only ripened orange, yellow and broken-white products
--	------------	------------------	---	--	---

6) in category 02.1 (Fats and oils essentially free from water (excluding anhydrous milkfat)), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	10		only fats
--	-----------	---------------	----	--	-----------

- 7) in category 02.2.2 (Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	10		excluding reduced fat butter
--	-----------	---------------	----	--	------------------------------

- 8) in category 03 (Edible ices), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	20		
--	------------	------------------	----	--	--

- 9) Category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	except chestnut purée
	E 160b(ii)	Annatto norbixin	20	(94)	except chestnut purée

- (ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

10) Category 04.2.5.3 (Other similar fruit or vegetable spreads) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 142 (Green S):

	E 160b(i)	Annatto bixin	20	(94)	except <i>crème de pruneaux</i>
	E 160b(ii)	Annatto norbixin	20	(94)	except <i>crème de pruneaux</i>

- (ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

11) Category 04.2.6 (Processed potato products) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	10	(94)	only dried potato granules and flakes
	E 160b(ii)	Annatto norbixin	10	(94)	only dried potato granules and flakes

- (ii) the following footnote (94) is added after footnote (46):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

12) Category 05.2 (Other confectionery including breath freshening microsweets) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entries for E 124 (Ponceau 4R, Cochineal Red A):

	E 160b(i)	Annatto bixin	30	(94)	
	E 160b(ii)	Annatto norbixin	25	(94)	

- (ii) the following footnote (94) is added after footnote (72):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

13) Category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	80	(94)	only decorations and coatings
	E 160b(ii)	Annatto norbixin	20	(94)	only decorations and coatings

- (ii) the following footnote (94) is added after footnote (73):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

14) in category 06.3 (Breakfast cereals), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	20		only extruded puffed and or fruit-flavoured breakfast cereals
--	------------	------------------	----	--	---

15) Category 06.5 (Noodles) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for group II (Colours at *quantum satis*):

	E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

- (ii) the following footnote (94) is added after footnote (81):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

16) Category 06.6 (Batters) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	50	(94)	only batters for coating
	E 160b(ii)	Annatto norbixin	50	(94)	only batters for coating

- (ii) the following footnote (94) is added after footnote (81):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'



17) in category 07.2 (Fine bakery wares), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	10		
--	------------	------------------	----	--	--

18) Category 08.2 (Meat preparations as defined by Regulation (EC) No 853/2004) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 150a-d (Caramels):

	E 160b(i)	Annatto bixin	20	(94)	only <i>breakfast sausages</i> with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance
	E 160b(ii)	Annatto norbixin	20	(94)	only <i>breakfast sausages</i> with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those

					products their typical appearance
--	--	--	--	--	-----------------------------------

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

19) Category 08.3.1 (Non-heat-treated meat products) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	only <i>chorizo sausage, salchichon, pasturmas</i> and <i>sobrasada</i>
	E 160b(ii)	Annatto norbixin	20	(94)	only <i>chorizo sausage, salchichon, pasturmas</i> and <i>sobrasada</i>

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

20) Category 08.3.2 (Heat-treated meat products) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	only sausages, pâtés, terrines and <i>luncheon meat</i>
	E 160b(ii)	Annatto norbixin	20	(94)	only sausages, pâtés, terrines and <i>luncheon meat</i>

- (ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

21) Category 08.3.3 (Casings and coatings and decorations for meat) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	50	(94)	
	E 160b(ii)	Annatto norbixin	50	(94)	

- (ii) the following footnote (94) is added after footnote (89):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

22) Category 09.2 (Processed fish and fishery products including molluscs and crustaceans) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) concerning ‘only smoked fish’ is replaced by the following new entries for Annatto bixin and Annatto norbixin, respectively for ‘only smoked fish’ and for ‘only surimi and similar products and salmon substitutes’:

	E 160b(i)	Annatto bixin	10	(94)	only smoked fish
	E 160b(i)	Annatto bixin	30	(94)	only surimi and similar products and salmon substitutes
	E 160b(ii)	Annatto norbixin	10	(94)	only smoked fish
	E 160b(ii)	Annatto norbixin	30	(94)	only surimi and similar products and salmon substitutes

- (ii) the following footnote (94) is added after footnote (85):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

23) Category 12.5 (Soups and broths) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for Group III (Colours with combined maximum limit):

	E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	10	(94)	

(ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

24) Category 12.6 (Sauces) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 110 (Sunset Yellow FCF/Orange Yellow S):

	E 160b(i)	Annatto bixin	30	(94)	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces
	E 160b(ii)	Annatto norbixin	30	(94)	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces

(ii) the following footnote (94) is added after footnote (65):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

25) in category 14.1.4 (Flavoured drinks), the following new entry for E 160b(i) (Annatto bixin) is inserted after the entry for E 124 (Ponceau 4R, Cochineal Red A):

	E 160b(i)	Annatto bixin	20		
--	-----------	---------------	----	--	--

- 26) in category 14.2.6 (Spirit drinks as defined in Regulation (EC) No 110/2008), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	10		only liqueurs
--	-----------	---------------	----	--	---------------

- 27) in category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	10		only alcoholic drinks with less than 15 % of alcohol
--	------------	------------------	----	--	--

- 28) Category 15.1 (Potato-, cereal-, flour- or starch-based snacks) is amended as follows:

- (i) the two entries for E 160b (Annatto, Bixin, Norbixin) are replaced by the following:

	E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

- (ii) the following footnote (94) is added after footnote (71):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

- 29) Category 15.2 (Processed nuts) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	10	(94)	
	E 160b(ii)	Annatto norbixin	10	(94)	

(ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

30) Category 16 (Desserts excluding products covered in category 1, 3 and 4) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	7.5	(94)	

(ii) the following footnote (94) is added after footnote (74):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels should not be exceeded.'

(2) In Part 2 of Annex III to Regulation (EC) No 1333/2008, the entry for E 900 (Dimethyl polysiloxane) is replaced by the following:

E 900	Dimethyl polysiloxane	200 mg/kg in the preparation, 0,2 mg/l in final food	Colour preparations of E 160a carotenes, E 160b(i) annatto bixin, E 160b(ii) annatto norbixin, E 160c paprika extract, capsanthin, capsorubin, E 160d lycopene and E 160e beta-apo-8'-carotenal
-------	-----------------------	--	---

DRAFT



## ANNEX II

In the Annex to Regulation (EU) No 231/2012, the respective entries for E 160b Annatto, Bixin, Norbixin: (i) Solvent-extracted bixin and norbixin, (ii) alkali extracted annatto and (iii) oil extracted annatto are replaced by the following:

### **E 160 b (i) ANNATTO BIXIN**

<b>(I) SOLVENT-EXTRACTED BIXIN</b>	
<b>Synonyms</b>	Annatto B, Orlean, Terre orellana, L. Orange, Natural Orange 4
<b>Definition</b>	<p>Solvent-extracted bixin is obtained by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide. The resulting preparation may be acidified, followed by the removal of the solvent, drying and milling.</p> <p>Solvent-extracted bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo- $\Psi$ , $\Psi$ -

	carotenedioate	
Chemical formula	cis-Bixin: C <sub>25</sub> H <sub>30</sub> O <sub>4</sub>	
Molecular weight	394,5	
Assay	Not less than 85 % colouring matter (expressed as bixin) E <sup>1%</sup> <sub>1cm</sub> 3090 at ca. 487 nm in tetrahydrofuran and acetone	
<b>Description</b>	Dark red-brown to red-purple powder	
<b>Identification</b>		
Solubility	Insoluble in water, slightly soluble in ethanol	
Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm	
<b>Purity</b>		
Norbixin	Not more than 5 % of total colouring matters	
Residual Solvents	Acetone: Not more than 30 mg/kg Methanol: Not more than 50 mg/kg Hexane: Not more than 25 mg/kg	
	Ethanol: Isopropyl alcohol: Ethyl acetate:	not more than 50 mg/kg, singly or in combination
Arsenic	Not more than 2 mg/kg	

Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(II) AQUEOUS-PROCESSED BIXIN	
<b>Synonyms</b>	Annatto E, Orlean, Terre orellana, L. Orange
<b>Definition</b>	<p>Aqueous-processed bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) by abrading the seeds in the presence of cold, mildly-alkaline water. The resultant preparation is acidified to precipitate bixin which is then filtered, dried and milled.</p> <p>Aqueous-processed bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo-Ψ,Ψ-carotenedioate
Chemical formula	cis-Bixin: C <sub>25</sub> H <sub>30</sub> O <sub>4</sub>
Molecular weight	394,5

Assay	Not less than 25 % colouring matter (expressed as bixin) E <sup>1%</sup> <sub>1cm</sub> 3090 at ca. 487 nm in tetrahydrofuran and acetone
<b>Description</b>	Dark red-brown to red-purple powder
<b>Identification</b>	
Solubility	Insoluble in water, slightly soluble in ethanol
Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
<b>Purity</b>	
Norbixin	Not more than 7 % of total colouring matters
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

#### E 160 b (ii) ANNATTO NORBIXIN

(I) SOLVENT-EXTRACTED NORBIXIN	
<b>Synonyms</b>	Annatto C, Orlean, Terre orellana, L. Orange, Natural Orange 4
<b>Definition</b>	Solvent-extracted norbixin is obtained from the outer coating of the seeds of the annatto tree ( <i>Bixa orellana</i> L.)

	<p>by washing with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide followed by solvent removal, crystallization and drying. Aqueous alkali is added to the resultant powder, which is then heated to hydrolyse the colouring matter and cooled. The aqueous solution is filtered, and acidified to precipitate the norbixin. The precipitate is filtered, washed, dried and milled, to give a granular powder.</p> <p>Solvent-extracted norbixin contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	208-810-8
Chemical name	<p><i>cis</i>-Norbixin: 6,6'-Diapo-<math>\Psi</math>,<math>\Psi</math>-carotenedioic acid</p> <p><i>cis</i>-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-<math>\Psi</math>,<math>\Psi</math>-carotenedioate</p> <p><i>cis</i>-Norbixin disodium salt: Disodium 6,6'-diapo-<math>\Psi</math>,<math>\Psi</math>-carotenedioate</p>
Chemical formula	<p><i>cis</i>-Norbixin: C<sub>24</sub>H<sub>28</sub>O<sub>4</sub></p> <p><i>cis</i>-Norbixin dipotassium salt: C<sub>24</sub>H<sub>26</sub>K<sub>2</sub>O<sub>4</sub></p>

	<i>cis</i> -Norbixin disodium salt: C <sub>24</sub> H <sub>26</sub> Na <sub>2</sub> O <sub>4</sub>	
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)	
Assay	Not less than 85 % colouring matter (expressed as norbixin) E <sup>1%</sup> <sub>1cm</sub> 2870 at ca. 482 nm in 0,5% potassium hydroxide solution	
<b>Description</b>	Dark red-brown to red-purple powder	
<b>Identification</b>		
Solubility	Soluble in alkaline water, slightly soluble in ethanol	
Spectrometry	The sample in 0,5% potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm	
<b>Purity</b>		
Residual Solvents	Acetone: Not more than 30 mg/kg Methanol: Not more than 50 mg/kg Hexane: Not more than 25 mg/kg	
	Ethanol: Isopropyl alcohol: Ethyl acetate:	not more than 50 mg/kg, singly or in combination
Arsenic	Not more than 2 mg/kg	
Lead	Not more than 1 mg/kg	
Mercury	Not more than 1 mg/kg	

Cadmium	Not more than 0,5 mg/kg
---------	-------------------------

(II) ALKALI-PROCESSED NORBIXIN, ACID-PRECIPIATED	
<b>Synonyms</b>	Annatto F, Orlean, Terre orellana, L. Orange, Natural Orange 4
<b>Definition</b>	<p>Alkali-processed norbixin (acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution and is acidified to precipitate the norbixin. The precipitate is filtered, dried and milled to give a granular powder.</p> <p>Alkali-processed norbixin contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	208-810-8
Chemical name	<p><i>cis</i>-Norbixin: 6,6'-Diapo-<math>\Psi</math>,<math>\Psi</math>-carotenedioic acid</p> <p><i>cis</i>-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-<math>\Psi</math>,<math>\Psi</math>-carotenedioate</p> <p><i>cis</i>-Norbixin disodium salt: Disodium 6,6'-diapo-<math>\Psi</math>,<math>\Psi</math>-carotenedioate</p>

Chemical formula	<i>cis</i> -Norbixin: C <sub>24</sub> H <sub>28</sub> O <sub>4</sub> <i>cis</i> -Norbixin dipotassium salt: C <sub>24</sub> H <sub>26</sub> K <sub>2</sub> O <sub>4</sub> <i>cis</i> -Norbixin disodium salt: C <sub>24</sub> H <sub>26</sub> Na <sub>2</sub> O <sub>4</sub>
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 35 % colouring matter (expressed as norbixin) E <sup>1%</sup> <sub>1cm</sub> 2870 at ca. 482 nm in 0,5% potassium hydroxide solution
<b>Description</b>	Dark red-brown to red-purple powder
<b>Identification</b>	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5% potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
<b>Purity</b>	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(III) ALKALI-PROCESSED NORBIXIN, NOT ACID-PRECIPIATED	
<b>Synonyms</b>	Annatto G, Orlean, Terre orellana, L. Orange, Natural



	Orange 4
<b>Definition</b>	<p>Alkali-processed norbixin (not acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution. The precipitate is filtered, dried and milled to give a granular powder. Extracts contain mainly the potassium or sodium salt of norbixin as the major colouring matter.</p> <p>Alkali-processed norbixin (not acid-precipitated) contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	208-810-8
Chemical name	<p><i>cis</i>-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid</p> <p><i>cis</i>-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate</p> <p><i>cis</i>-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate</p>
Chemical formula	<p><i>cis</i>-Norbixin: C<sub>24</sub>H<sub>28</sub>O<sub>4</sub></p> <p><i>cis</i>-Norbixin dipotassium salt: C<sub>24</sub>H<sub>26</sub>K<sub>2</sub>O<sub>4</sub></p> <p><i>cis</i>-Norbixin disodium salt: C<sub>24</sub>H<sub>26</sub>Na<sub>2</sub>O<sub>4</sub></p>

Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 15 % colouring matter (expressed as norbixin) E <sup>1%</sup> <sub>1cm</sub> 2870 at ca. 482 nm in 0,5% potassium hydroxide solution
<b>Description</b>	Dark red-brown to red-purple powder
<b>Identification</b>	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5% potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
<b>Purity</b>	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg