

Official Journal of the European Union

L 74



English edition

Legislation

Volume 64

4 March 2021

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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/381

of 25 February 2021

entering a name in the register of protected designations of origin and protected geographical indications ('Escavèche de Chimay' (PGI))

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Belgium's application to register the name 'Escavèche de Chimay' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Escavèche de Chimay' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Escavèche de Chimay' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 340, 13.10.2020, p. 12.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 February 2021.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION REGULATION (EU) 2021/382**of 3 March 2021****amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽¹⁾, and in particular Article 13(1)(c) and (d) thereof,

Whereas:

- (1) Regulation (EC) No 852/2004 lays down general rules for food business operators on the hygiene of foodstuffs taking into account the principle that it is necessary to ensure food safety throughout the food chain, starting with primary production. Food business operators therefore, need to comply with the general hygiene provisions laid down in Annexes I and II of that Regulation.
- (2) On 30 October 2014, the European Food Safety Authority ('the Authority') updated its scientific advice on the evaluation of allergenic foods and food ingredients for labelling purposes ⁽²⁾, indicating that the presence of food allergies across Europe has been estimated at 3 % to 4 % for both adults and children. The Authority concluded that, while food allergies affect a relatively small proportion of the population, an allergic reaction can be severe, even potentially fatal and that it is increasingly apparent that people with food allergies or intolerances experience a very significant reduction in quality of life.
- (3) In September 2020, the Codex Alimentarius Commission adopted a code of practice on food allergen management for food business operators (CXC 80-2020) including recommendations on the mitigation of food allergens by a harmonised approach in the food chain based on general hygiene requirements.
- (4) Considering the adoption of the global standard CXC 80-2020 and the expectations of consumers and trade partners that food produced in the EU complies at least with such global standard, it is necessary to introduce requirements introducing good hygiene practices to prevent or limit the presence of substances causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, in equipment, conveyances and/or containers used for the harvesting, transport or storage of foodstuffs. Since contamination of foodstuffs might take place both at the level of primary production and at stages beyond that production, both Annexes I and II to Regulation (EC) No 852/2004 should be amended.
- (5) The Farm to Fork Strategy for a fair, healthy and environmental friendly food system, adopted by the Commission, is a key component of the European Green Deal initiative. Reducing food waste is one of the objectives of the Farm to Fork Strategy which will also contribute to achieving a circular economy. Redistribution of food surplus for human consumption, in particular through food donations, where it is safe to do so, ensures the highest value use of edible food resources, while preventing food waste.
- (6) On 27 September 2018, the Authority adopted a second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations ⁽³⁾. In the opinion, it states that food donations presents several new food safety challenges at retail level and therefore it recommends several additional general hygiene requirements. It is therefore necessary to lay down certain requirements in order to promote and facilitate redistribution of food, while guaranteeing its safety for consumers.

⁽¹⁾ OJ L 139, 30.4.2004, p. 1.

⁽²⁾ <http://www.efsa.europa.eu/sites/default/files/consultation/140523.pdf>

⁽³⁾ EFSA Journal 2018; 16(11):5432

- (7) In September 2020, the Codex Alimentarius Commission adopted a revision of its global standard on *General Principles of Food Hygiene* (CXC 1-1969). The revised CXC 1-1969 introduces the 'food safety culture' concept as a general principle. Food safety culture enhances food safety by increasing the awareness and improving behaviour of employees in food establishments. Such impact on food safety has been demonstrated in several scientific publications.
- (8) Considering the revision of the global standard and the expectations of consumers and trade partners that food produced in the EU complies at least with such global standard, it is necessary to include general requirements on food safety culture in Regulation (EC) No 852/2004.
- (9) Regulation (EC) No 852/2004 should be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Regulation (EC) No 852/2004 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

- (1) Annex I to Regulation (EC) No 852/2004 is amended as follows:

In Part A, Section II, the following point 5a is inserted:

‘5a. Equipment, conveyances and/or containers used for the harvesting, transport or storage of one of the substances or products causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the harvesting, transport or storage of any food not containing that substance or product, unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product.’

- (2) Annex II to Regulation (EC) No 852/2004 is amended as follows:

- (a) the introduction is replaced by the following:

‘INTRODUCTION

Chapters V, Va, VI, VII, VIII, IX, X, XI, XIa and XII apply to all stages of production, processing and distribution of food. The remaining Chapters apply as follows:

- Chapter I applies to all food premises, except premises to which Chapter III applies,
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies,
- Chapter III applies to those premises listed in the heading of that Chapter,
- Chapter IV applies to all transportation;’

- (b) the following Chapter Va is inserted after Chapter V:

‘CHAPTER Va

Redistribution of food

Food business operators may redistribute food for the purpose of food donation subject to the following conditions:

- (1) Food business operators shall routinely check if food under their responsibility is not injurious to health and is fit for human consumption in accordance with Article 14(2) of Regulation (EC) No 178/2002 (*). If the check carried out is satisfactory, food business operators may redistribute food in accordance with point (2):
 - for food for which a “use by” date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011, before the expiry of that date,
 - for food for which a date of minimum durability is applied in accordance with Article 2(2)(r) of Regulation (EU) No 1169/2011, up to and after that date, or
 - for food for which a date of minimum durability is not required in accordance with point 1(d) of Annex X to Regulation (EU) No 1169/2011, at any time provided.
- (2) Food business operators handling food referred to in point 1, shall assess if food is not injurious to health and fit for human consumption by taking into account at least the following:
 - the date of minimum durability or the “use by” date, ensuring sufficient remaining shelf-life left to allow for the safe redistribution and use by the final consumer,
 - the integrity of the packaging, when applicable,
 - the proper storage and transport conditions, including applicable temperature requirements,
 - the date of freezing in accordance with point 2(b) of Section IV of Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council (**), when applicable,
 - the organoleptic conditions,

- the assurance of traceability in accordance with Commission Implementing Regulation (EU) No 931/2011 (**), in case of products of animal origin.

- (*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).
- (**) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).
- (***) Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin (OJ L 242, 20.9.2011, p. 2).;

(c) in Chapter IX, the following point 9 is inserted:

- ‘9. Equipment, conveyances and/or containers used for the processing, handling, transport or storage of one of the substances or products causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the processing, handling, transport or storage of any food, not containing that substance or product, unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product.’;

(d) the following Chapter XIa is inserted after Chapter XI:

‘CHAPTER XIa

Food Safety Culture

1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements:
 - (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food;
 - (b) leadership towards the production of safe food and to engage all employees in food safety practices;
 - (c) awareness of food safety hazards and of the importance of food safety and hygiene by all employees in the business;
 - (d) open and clear communication between all employees in the business, within an activity and between consecutive activities, including communication of deviations and expectations;
 - (e) availability of sufficient resources to ensure the safe and hygienic handling of food.
2. Management commitment shall include:
 - (a) ensuring that roles and responsibilities are clearly communicated within each activity of the food business;
 - (b) maintaining the integrity of the food hygiene system when changes are planned and implemented;
 - (c) verifying that controls are being performed timely and efficiently and documentation is up to date;
 - (d) ensuring that the appropriate training and supervision are in place for personnel;
 - (e) ensuring compliance with relevant regulatory requirements;
 - (f) encouraging continual improvement of the food safety management system of the business, where appropriate, taking into account developments in science, technology and best practices.
3. The implementation of the food safety culture shall take account of the nature and size of the food business.’

COMMISSION REGULATION (EU) 2021/383**of 3 March 2021****amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council
listing co-formulants which are not accepted for inclusion in plant protection products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 27(2) and Article 78(2) thereof,

Whereas:

- (1) Co-formulants are described in point (c) of Article 2(3) of Regulation (EC) No 1107/2009 as substances or preparations, which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists.
- (2) Co-formulants are unacceptable in plant protection products if their residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment. Co-formulants are also unacceptable in plant protection products if their use, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or have an unacceptable effect on plants, plant products or the environment. Such unacceptable co-formulants are to be listed in Annex III to Regulation (EC) No 1107/2009.
- (3) Co-formulants are substances or preparations used together with active substances in plant protection products and are thus equally spread in the environment. Therefore, the criteria concerning human health, the environment, ecotoxicity and groundwater, provided for in points 3.6.2, 3.6.3, 3.6.4, 3.6.5, 3.7, 3.8.2 and 3.10 of Annex II to Regulation (EC) No 1107/2009, should also be relevant to identify unacceptable co-formulants.
- (4) The list of unacceptable co-formulants thus should include substances with a harmonised classification as carcinogens, category 1A or 1B, as mutagens, category 1A or 1B, or as toxic to reproduction, category 1A or 1B, in accordance with Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾.
- (5) The list of unacceptable co-formulants should further include substances identified as persistent, bioaccumulative and toxic ('PBT') or very persistent and very bioaccumulative ('vPvB') in accordance with points (d) and (e) of Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (6) The list of unacceptable co-formulants should also include substances of very high concern due to endocrine disrupting properties in accordance with point (f) of Article 57 of Regulation (EC) No 1907/2006 or substances identified as endocrine disruptors under Regulation (EC) No 528/2012 of the European Parliament and of the Council ⁽⁴⁾ or substances identified as persistent organic pollutants (‘POP’) under Regulation (EU) 2019/1021 of the European Parliament and of the Council ⁽⁵⁾.
- (7) Regulation (EC) No 1907/2006 sets out restrictions for certain dangerous substances in its Annex XVII. Where the use of those substances is subject to restrictions as co-formulants in plant protection products, they should be added to the list of co-formulants in Annex III to Regulation (EC) No 1107/2009.
- (8) Member States have identified co-formulants that they found unacceptable in plant protection products authorised under Council Directive 91/414/EEC ⁽⁶⁾ or Regulation (EC) No 1107/2009. Such co-formulants have been notified by Austria, Belgium, France, Germany, Italy, Lithuania, Spain and Norway. Amongst those co-formulants, those with a harmonised classification as carcinogens, category 1A or 1B, as mutagens, category 1A or 1B, or as toxic to reproduction, category 1A or 1B, in accordance with Annex VI to Regulation (EC) No 1272/2008, those identified as PBT or vPvB according to points (d) and (e) of Article 57 of Regulation (EC) No 1907/2006, those identified as substances of very high concern due to endocrine disrupting properties in accordance with point (f) of Article 57 of Regulation (EC) No 1907/2006, and those identified as POP under Regulation (EU) 2019/1021 should be listed in Annex III to Regulation (EC) No 1107/2009.
- (9) The use of polyethoxylated tallowamines (CAS No 61791-26-2) in plant protection products containing glyphosate was prohibited by Commission Implementing Regulation (EU) 2016/1313 ⁽⁷⁾, as concerns were identified in relation to the toxicity of polyethoxylated tallowamines and their potential to negatively affect human health. Given that those concerns are due to the intrinsic properties of the substances concerned and are thus not limited to formulated products containing glyphosate but are equally valid for formulated products containing other active substances, polyethoxylated tallowamines should also be added to the list of co-formulants in Annex III to Regulation (EC) No 1107/2009.
- (10) Commission Implementing Decisions (EU) 2016/109 ⁽⁸⁾ and (EU) 2018/619 ⁽⁹⁾ did not approve PHMB (1600; 1.8), CAS number 27083-27-8 and 32289-58-0, and PHMB (1415; 4.7), CAS number 32289-58-0 and 1802181-67-4, as existing active substances for use in biocidal products for product-type 6 (in-can preservatives), amongst other product types due to unacceptable risks for human health and the environment. Their use as in-can preservatives in plant protection products would, therefore, lead to unacceptable effects on human health and the environment. Consequently, PHMB (1600; 1.8) and PHMB (1415; 4.7) should also be listed in Annex III to Regulation (EC) No 1107/2009.
- (11) Co-formulants to be listed in Annex III to Regulation (EC) No 1107/2009 may also be contained in adjuvants placed on the market. As detailed rules for the authorisation of adjuvants, in accordance with Article 58(2) of Regulation (EC) No 1107/2009, have not yet been established, Member States may continue to apply national provisions as regards adjuvants in accordance with Article 81(3) of that Regulation. As Regulation (EC) No 1107/2009 aims to prevent the placing on the market or use of adjuvants containing prohibited co-formulants, it is necessary to ensure that also adjuvants, to be mixed with plant protection products, do not contain any of those unacceptable co-formulants.

⁽⁴⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

⁽⁵⁾ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

⁽⁶⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁷⁾ Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ L 208, 2.8.2016, p. 1).

⁽⁸⁾ Commission Implementing Decision (EU) 2016/109 of 27 January 2016 not to approve PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-types 1, 6 and 9 (OJ L 21, 28.1.2016, p. 84).

⁽⁹⁾ Commission Implementing Decision (EU) 2018/619 of 20 April 2018 not approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 1, 5 and 6 (OJ L 102, 23.4.2018, p. 21).

- (12) Member States should be provided with sufficient time to review the composition of the plant protection products and adjuvants currently authorised in their territory, in order to assess whether they contain co-formulants listed in Annex III to Regulation (EC) No 1107/2009 and to withdraw or amend authorisations for plant protection products and adjuvants containing those co-formulants.
- (13) For plant protection products or adjuvants containing a co-formulant listed in Annex III to Regulation (EC) No 1107/2009, where Member States grant any grace period in accordance with Article 46 of that Regulation or in accordance with national provisions for authorisation of adjuvants, respectively, that period should expire for the sale and distribution at the latest 3 months and for the disposal, storage and use additional 9 months after the date of amendment or withdrawal of the authorisations.
- (14) Co-formulants to be listed in Annex III to Regulation (EC) No 1107/2009 may be present as unintentional impurities in other co-formulants, which as such are acceptable for use in plant protection products or adjuvants. Therefore, the individual concentration of the unacceptable co-formulants in the finished plant protection product or adjuvant should be less than 0,1 % weight by weight (w/w) or less than a specific concentration limit related to CMR properties (carcinogenic, mutagenic and reprotoxic), when established in Annex VI to Regulation (EC) No 1272/2008 for the unacceptable co-formulant at a level lower than 0,1 % weight by weight (w/w), in order to be considered as acceptable unintentional impurity, unless a different limit is provided due to technical limitations of relevant analytical methods.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1107/2009 is amended in accordance with the Annex to this Regulation.

Article 2

Member States which have granted authorisations for plant protection products containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation, shall amend or withdraw those authorisations as soon as possible but no later than 24 March 2023.

Article 3

Member States shall not authorise the placing on the market or use of adjuvants containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation.

Member States which have authorised adjuvants containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation, shall amend or withdraw those authorisations as soon as possible but no later than 24 March 2023.

Article 4

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 or national provisions for authorisation of adjuvants shall be as short as possible and shall expire for the sale and distribution at the latest 3 months and for the disposal, storage and use additional 9 months after the date of amendment or withdrawal of the authorisations referred to in Articles 2 and 3.

Article 5

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

Annex III to Regulation (EC) No 1107/2009 is replaced by the following:

‘ANNEX III

List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27 ⁽¹⁾

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
1.	1-Chloro-2,3-epoxypropane	Epichlorohydrin, 2,3-Epoxypropyl chloride	106-89-8	203-439-8	Carcinogenic cat.1B
2.	1,2- Dichloroethane	1,2-Dichloroethane; Ethane, 1,2-dichloro-	107-06-2	203-458-1	Carcinogenic cat.1B
3.	2-Ethoxyethanol	2-Ethoxyethanol; Ethanol, 2-ethoxy-	110-80-5	203-804-1	Toxic to reproduction cat.1B
4.	2-Ethoxyethyl acetate	2-Ethoxyethanol acetate; Ethanol, 2-ethoxy-, 1-acetate	111-15-9	203-839-2	Toxic to reproduction cat.1B
5.	1-Ethylpyrrolidin-2-one	1-Ethylpyrrolidin-2-one; N-ethyl-2-pyrrolidone	2687-91-4	220-250-6	Toxic to reproduction cat.1B
6.	2-Methoxyethanol	2-Methoxyethanol; Ethanol, 2-methoxy-	109-86-4	203-713-7	Toxic to reproduction cat.1B
7.	2-Methoxyethyl acetate	2-Methoxyethyl acetate; Ethanol, 2-methoxy-, 1-acetate; 2-Methoxyethanol acetate	110-49-6	203-772-9	Toxic to reproduction cat.1B
8.	2-Methoxypropanol	2-Methoxypropanol; 1-Propanol, 2-methoxy-	1589-47-5	216-455-5	Toxic to reproduction cat.1B
9.	1-Methylpyrrolidin-2-one	1-Methyl-2-pyrrolidone; 2-Pyrrolidinone, 1-methyl-	872-50-4	212-828-1	Toxic to reproduction cat.1B

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
10.	2-Nitropropane	2-Nitropropane; Propane, 2-nitro-	79-46-9	201-209-1	Carcinogenic cat.1B
11.	Amines, tallow alkyl, ethoxylated	Amines, tallow alkyl, ethoxylated; POE-tallowamine	61791-26-2		Concerns or data gaps related to potential effects on human health or the environment
12.	Amines, tallow alkyl, ethoxylated propoxylated	Amines, tallow alkyl, ethoxylated propoxylated; POEP-tallowamine	68213-26-3		Concerns or data gaps related to potential effects on human health or the environment
13.	Asbestos fibres	Actinolite asbestos; Asbestos, actinolite	77536-66-4		Carcinogenic cat.1A
14.		Amosite asbestos; Asbestos, amosite	12172-73-5		Carcinogenic cat.1A
15.		Anthophyllite asbestos; Asbestos, anthophyllite	77536-67-5		Carcinogenic cat.1A
16.		Chrysotile asbestos; Asbestol, chrysotile	12001-29-5		Carcinogenic cat.1A
17.		Crocidolite asbestos; Asbestos, crocidolite	12001-28-4		Carcinogenic cat.1A
18.		Tremolite asbestos; Asbestos, tremolite	77536-68-6		Carcinogenic cat.1A
19.	Benzene	Benzene	71-43-2	200-753-7	Carcinogenic cat.1A/ Mutagenic cat.1B
20.	Benzo[def]chrysene; ⁽²⁾ Benzo[pqr]tetraphene	Benzo[def]chrysene; Benzo[a]pyrene	50-32-8	200-028-5	Carcinogenic cat.1B/Mutagenic cat.1B/ Toxic to reproduction cat.1B

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
21.	Bis(2-methylpropyl) benzene-1,2-dicarboxylate	Diisobutyl phthalate	84-69-5	201-553-2	Endocrine disrupting properties (REACH Article 57(f) – Human Health) Toxic to reproduction cat.1B
22.	Boric acid	Boric acid	10043-35-3 11113-50-1	233-139-2 234-343-4	Toxic to reproduction cat.1B
23.	Disodium octaborate	Disodium octaborate; Disodium octaborate anhydrous	12008-41-2	234-541-0	Toxic to reproduction cat.1B
24.	Disodium octaborate, tetrahydrate	Boric acid, disodium salt, tetrahydrate;	12280-03-4	234-541-0	Toxic to reproduction cat.1B
25.	Disodium tetraborate, anhydrous	Disodium tetraborate, anhydrous; Boron sodium oxide	1330-43-4	215-540-4	Toxic to reproduction cat.1B
26.	Disodium tetraborate, decahydrate	Borax	1303-96-4	215-540-4	Toxic to reproduction cat.1B
27.	Disodium tetraborate, pentahydrate	Boron sodium oxide, hydrated	12179-04-3	215-540-4	Toxic to reproduction cat.1B
28.	Orthoboric acid, sodium salt	Orthoboric acid, sodium salt; Boric acid, sodium salt	13840-56-7	237-560-2	Toxic to reproduction cat.1B
29.	Tetraboron disodium heptaoxide, hydrate	Tetraboron disodium heptaoxide, hydrate; Boron sodium oxide, hydrate	12267-73-1	235-541-3	Toxic to reproduction cat.1B
30.	Buta-1,3-diene	Buta-1,3-diene; 1,3-Butadiene	106-99-0	203-450-8	Carcinogenic cat.1A/ Mutagenic cat.1B
31.	Butane containing ≥ 0,1 % butadiene (EC No 203-450-8)	Butane	106-97-8	203-448-7	Carcinogenic cat.1A
32.	Co Poly (bisiminoimidocarbonyl, hexamethylene hydrochloride), (iminoimidocarbonyl, hexamethylene hydrochloride	Guanidine, N,N"-1,6-hexanediylbis[N'-cyano-, polymer with 1,6-hexanediamine, hydrochloride	27083-27-8 and		Not approved for use in biocidal products for product-type 6 (in-can preservatives).

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
		Poly[iminocarbonimidoyliminocarbonimidoylimino-1,6-hexanediyl], hydrochloride Cyanamide, N-cyano-, compd. with 1,6-hexanediamine (2:1), polymer with 1,6-hexanediamine hydrochloride (1:2); PHMB	32289-58-0 and 1802181-67-4		
33.	Dibutyl phthalate	<i>n</i> -Butyl phthalate; Dibutyl benzene-1,2-dicarboxylate	84-74-2	201-557-4	Endocrine disrupting properties (REACH Article 57(f) – Human Health) Toxic to reproduction cat.1B
34.	Distillates (petroleum), hydrotreated heavy naphthenic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64742-52-5	265-155-0	Carcinogenic cat.1B
35.	Distillates (petroleum), hydrotreated heavy paraffinic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64742-54-7	265-157-1	Carcinogenic cat.1B
36.	Distillates (petroleum), hydrotreated light naphthenic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64742-53-6	265-156-6	Carcinogenic cat.1B
37.	Distillates (petroleum), hydrotreated light paraffinic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64742-55-8	265-158-7	Carcinogenic cat.1B
38.	Distillates (petroleum), solvent-dewaxed heavy paraffinic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64742-65-0	265-169-7	Carcinogenic cat.1B

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
39.	Distillates (petroleum), solvent-refined heavy paraffinic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64741-88-4	265-090-8	Carcinogenic cat.1B
40.	Distillates (petroleum), solvent-refined light paraffinic with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		64741-89-5	265-091-3	Carcinogenic cat.1B
41.	Ethylene oxide	Ethylene oxide; Oxyrane; Epoxyethane	75-21-8	200-849-9	Carcinogenic cat.1B/ Mutagenic cat. 1B
42.	Formaldehyde	Formaldehyde; Formalin; Methanal; Formol	50-00-0	200-001-8	Carcinogenic cat.1B
43.	Formamide	Formamide; Methanamide	75-12-7	200-842-0	Toxic to reproduction cat.1B
44.	Isobutane (containing $\geq 0,1$ % butadiene (EC No 203-450-8))	Isobutane; Propane, 2-methyl-	75-28-5	200-857-2	Carcinogenic cat.1A/ Mutagenic cat. 1B
45.	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based, high-viscosity with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		72623-85-9	276-736-3	Carcinogenic cat.1B
46.	Lubricating oils (petroleum), C15-30, hydrotreated neutral oil-based with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		72623-86-0	276-737-9	Carcinogenic cat.1B
47.	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		72623-87-1	276-738-4	Carcinogenic cat.1B

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
48.	Lubricating oils (petroleum), C17-32, solvent-extd., dewaxed, hydrogenated with a content of $\geq 3,0$ % DMSO-extract (measured by IP 346)		101316-70-5	309-875-6	Carcinogenic cat.1B
49.	Naphtha (petroleum), heavy alkylate predominantly branched chain C9-C12 with a content of $\geq 0,1$ % benzene (EC No 200-753-7)		64741-65-7	265-067-2	Carcinogenic cat.1B/ Mutagenic cat.1B
50.	Naphtha (petroleum), hydrodesulfurized heavy predominantly C7-C12 with a content of $\geq 0,1$ % benzene (EC No 200-753-7)		64742-82-1	265-185-4	Carcinogenic cat.1A/ Mutagenic cat.1B
51.	Naphtha (petroleum), hydrodesulfurized light, dearomatized predominantly C7 paraffins and cycloparaffins with a content of $\geq 0,1$ % benzene (EC No 200-753-7)		92045-53-9	295-434-2	Carcinogenic cat.1A/ Mutagenic cat.1B
52.	Naphtha (petroleum), hydrotreated heavy predominantly C6-C13 with a content of $\geq 0,1$ % benzene (EC No 200-753-7)		64742-48-9	265-150-3	Carcinogenic cat.1A/ Mutagenic cat.1B
53.	Naphtha (petroleum), light aromatic predominantly C8-C10 with a content of $\geq 0,1$ % benzene (EC N. 200-753-7)		64742-95-6	265-199-0	Carcinogenic cat.1A/ Mutagenic cat.1B
54.	Nitrobenzene	Nitrobenzene; Benzene, nitro-	98-95-3	202-716-0	Toxic to reproduction cat.1B
55.	N-methylformamide	N-methylformamide; Formamide, N-methyl-	123-39-7	204-624-6	Toxic to reproduction cat.1B

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
56.	Nonyl-phenols: Substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in any position to phenol, covering also substances which include any of the individual isomers or a combination thereof.	4-(3,5-Dimethylheptan-3-yl)phenol Phenol, 4-(1-ethyl-1,3-dimethylpentyl)-; 4-(1-Ethyl-1,3-dimethylpentyl)phenol	186825-36-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)
57.		4-(3,6-Dimethylheptan-3-yl)phenol Phenol, 4-(1-ethyl-1,4-dimethylpentyl)-; 4-(1-Ethyl-1,4-dimethylpentyl)phenol	142731-63-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)
58.		4-(2-Methyloctan-2-yl)phenol <i>p</i> -(1,1-Dimethylheptyl)phenol; Phenol, 4-(1,1-dimethylheptyl)-	30784-30-6	250-339-5	Endocrine disrupting properties (REACH Article 57(f) – Environment)
59.		4-(3-Methyloctan-3-yl)phenol Phenol, 4-(1-ethyl-1-methylhexyl)-; 4-(1-Ethyl-1-methylhexyl)phenol;	52427-13-1	257-907-1	Endocrine disrupting properties (REACH Article 57(f) – Environment)
60.		4-Nonylphenol <i>p</i> -Nonylphenol; Phenol, 4-nonyl-	104-40-5	203-199-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)
61.		Isononylphenol	11066-49-2	234-284-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)
62.		<i>p</i> -Isononylphenol; Phenol, 4-isononyl-	26543-97-5	247-770-6	Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
63.		Nonylphenol; Phenol, nonyl-	25154-52-3	246-672-0	Endocrine disrupting properties (REACH Article 57(f) – Environment)
64.		Phenol, 4-(1-methyloctyl)-; <i>p</i> -(1-Methyloctyl)phenol	17404-66-9	241-427-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)
65.		Phenol, 4-nonyl-, branched	84852-15-3	284-325-5	Endocrine disrupting properties (REACH Article 57(f) – Environment)
66.		Phenol, nonyl-, branched	90481-04-2	291-844-0	Endocrine disrupting properties (REACH Article 57(f) – Environment)
67.	Nonyl-phenols, ethoxylated: Substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in any position to phenol, ethoxylated, covering also substances which include any of the individual isomers or a combination thereof.	Nonylphenol, ethoxylated; Poly(oxy-1,2-ethanediyl), α -(nonylphenyl)- ω -hydroxy-		500-024-6	Endocrine disrupting properties (REACH Article 57(f) – Environment)
68.		4-Nonylphenol, branched, 1 – 2,5 moles ethoxylated Poly(oxy-1,2-ethanediyl), α -(4-nonylphenyl)- ω -hydroxy-, branched		500-315-8	Endocrine disrupting properties (REACH Article 57(f) – Environment)
69.		4-Nonylphenol, 1 – 2,5 moles ethoxylated		500-045-0	Endocrine disrupting properties (REACH Article 57(f) – Environment)
70.		2-(2-{2-[2-(4-Nonylphenoxy)ethoxy]ethoxy}ethoxy)ethan-1-ol 2-[2-[2-[2-(4-Nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol; Ethanol, 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]-	7311-27-5	230-770-5	Endocrine disrupting properties (REACH Article 57(f) – Environment)
71.		2-[2-(4-Nonylphenoxy)ethoxy]ethanol; Ethanol, 2-[2-(4-nonylphenoxy)ethoxy]-	20427-84-3	243-816-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
72.		20-(4-Nonylphenoxy)-3,6,9,12,15,18-hexaoxaicosan-1-ol; 3,6,9,12,15,18-Hexaoxaicosan-1-ol, 20- (4-nonylphenoxy)-	27942-27-4	248-743-1	Endocrine disrupting properties (REACH Article 57(f) – Environment)
73.		2-[2-[2-(4-Nonylphenoxy)ethoxy]ethoxy]ethoxy]ethan-1-ol Ethanol,2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]-	7311-27-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)
74.		26-(4-Nonylphenoxy)-3,6,9,12,15,18,21,24-octaoxahexacosan-1-ol 3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-(4-nonylphenoxy)-	14409-72-4		Endocrine disrupting properties (REACH Article 57(f) – Environment)
75.		17-(4-Nonylphenoxy)-3,6,9,12,15-pentaoxaheptadecan-1-ol 3,6,9,12,15-Pentaoxaheptadecan-1-ol, 17-(4-nonylphenoxy)-	34166-38-6		Endocrine disrupting properties (REACH Article 57(f) – Environment)
76.		Poly(oxy-1,2-ethanediyl), α -(4-nonylphenyl)- ω -hydroxy-, branched	127087-87-0		Endocrine disrupting properties (REACH Article 57(f) – Environment)
77.		Poly(oxy-1,2-ethanediyl), α -(4-nonylphenyl)- ω -hydroxy-	26027-38-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)
78.		Ethanol, 2-(4-nonylphenoxy)	104-35-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
79.		Isononylphenol, ethoxylated; Poly(oxy-1,2-ethanediyl), α -(isononylphenyl)- ω -hydroxy-	37205-87-1		Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
80.		2-[2-(4- <i>tert</i> -Nonylphenoxy) ethoxy] ethanol Ethanol, 2-[2-(4- <i>tert</i> -nonylphenoxy)ethoxy]-	156609-10-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
81.		Poly(oxy-1,2-ethanediyl), α -(nonylphenyl)- ω - hydroxy- Nonylphenol, ethoxylated	9016-45-9		Endocrine disrupting properties (REACH Article 57(f) – Environment)
82.	Octyl-phenols: Substances with a linear and/or branched alkyl chain with a carbon number of 8 covalently bound in any position to phe- nol, covering also substances which include any of the individual isomers or a combination thereof.	<i>p</i> -Octylphenol; 4-Octylphenol	1806-26-4	217-302-5	Endocrine disrupting properties (REACH Article 57(f) – Environment)
83.		4-(2,4,4-Trimethylpentan-2-yl)phenol; 4-(1,1,3,3-Tetramethylbutyl)phenol; 4-(<i>tert</i> -octyl) Phenol Phenol, 4-(1,1,3,3-tetramethylbutyl)-; 4- <i>tert</i> -Octylphenol	140-66-9	205-426-2	Endocrine disrupting properties (REACH Article 57(f) – Environment)
84.		Octylphenol; Phenol, octyl-	67554-50-1	266-717-8	Endocrine disrupting properties (REACH Article 57(f) – Environment)
85.		Phenol, 2-isooctyl-	86378-08-7		Endocrine disrupting properties (REACH Article 57(f) – Environment)
86.		Phenol, isooctyl-; Isooctylphenol	11081-15-5	234-304-1	Endocrine disrupting properties (REACH Article 57(f) – Environment)
87.		Phenol, 2-octyl-; <i>o</i> -Octylphenol	949-13-3	213-437-9	Endocrine disrupting properties (REACH Article 57(f) – Environment)
88.		Phenol, 2- <i>sec</i> -octyl-; <i>o-sec</i> -Octylphenol	26401-75-2	247-663-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
89.		Phenol, 4-isooctyl-; <i>p</i> -Isooctylphenol	27013-89-4	248-164-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)
90.		Phenol, 4- <i>sec</i> -octyl-; <i>p-sec</i> -Octylphenol	27214-47-7	248-330-6	Endocrine disrupting properties (REACH Article 57(f) – Environment)
91.		Phenol, <i>sec</i> -octyl-; <i>sec</i> -Octylphenol	93891-78-2	299-461-0	Endocrine disrupting properties (REACH Article 57(f) – Environment)
92.		Phenol, 4-(1-ethylhexyl)-; <i>p</i> -(1-Ethylhexyl)phenol	3307-00-4	221-989-7	Endocrine disrupting properties (REACH Article 57(f) – Environment)
93.		Phenol, 2-(1-methylheptyl)-; <i>o</i> -(1Methylheptyl)phenol	18626-98-7	242-459-1	Endocrine disrupting properties (REACH Article 57(f) – Environment)
94.		Phenol, 2-(1-ethylhexyl)-; <i>o</i> -(1-Ethylhexyl)phenol	17404-44-3	241-426-9	Endocrine disrupting properties (REACH Article 57(f) – Environment)
95.		Phenol, 2-(1-propylpentyl)-; <i>o</i> -(1-Propylpentyl)phenol	37631-10-0	253-574-1	Endocrine disrupting properties (REACH Article 57(f) – Environment)
96.		Phenol, 4-(1-propylpentyl)-; <i>p</i> -(1-Propylpentyl)phenol	3307 - 01-5	221-990-2	Endocrine disrupting properties (REACH Article 57(f) – Environment)
97.		Phenol, 2-(1-methylheptyl)-; <i>o</i> -(1,1,3,3-Tetramethylbutyl)phenol	3884-95-5	223-420-8	Endocrine disrupting properties (REACH Article 57(f) – Environment)
98.		Phenol, (1,1,3,3-tetramethylbutyl)-; (1,1,3,3-Tetramethylbutyl)phenol	27193-28-8	248-310-7	Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
99.		Phenol, (1-methylheptyl)-; (1-Methylheptyl)phenol	27985-70-2	248-759-9	Endocrine disrupting properties (REACH Article 57(f) – Environment)
100.		Phenol, 4-(2-methylheptyl)-	898546-19-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)
101.		Phenol, 2-(2-ethylhexyl)-	28752-62-7		Endocrine disrupting properties (REACH Article 57(f) – Environment)
102.		Phenol, 4-(1-methylheptyl)-; <i>p</i> -(1-Methylheptyl)phenol	1818-08-2	217-332-9	Endocrine disrupting properties (REACH Article 57(f) – Environment)
103.		Phenol, 4-(2-ethylhexyl)-	69468-20-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
104.		Phenol, 4-(5-methylheptyl)-	1824164-95-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)
105.		Phenol, 2-(2-methylheptyl)-	898546-20-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
106.		Phenol, 4-(2-propylpentyl)-	119747-99-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
107.		Phenol, 3-octyl-	20056-69-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)
108.		Phenol, 2-(1,1-dimethylhexyl)-	1824575-79-2		Endocrine disrupting properties (REACH Article 57(f) – Environment)
109.		Phenol, 4-(1,1-dimethylhexyl)-	30784-29-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
110.		Phenol, 4-(5,5-dimethylhexyl)-	13330-52-4		Endocrine disrupting properties (REACH Article 57(f) – Environment)
111.		Phenol, 2-(5,5-dimethylhexyl)-	1822989-97-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
112.		Phenol, 3-(1,1-dimethylhexyl)-	70435-92-6		Endocrine disrupting properties (REACH Article 57(f) – Environment)
113.		Phenol, 4-(1,4-dimethylhexyl)-	164219-26-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)
114.	Octyl-phenols, ethoxylated: Substances with a linear and/or branched alkyl chain with a carbon number of 8 covalently bound in any position to phenol, ethoxylated, covering also substances which include any of the individual isomers or a combination thereof.	Poly(oxy-1,2-ethanediyl), α-[(1,1,3,3-tetramethylbutyl) phenyl]-ω-hydroxy-2-(2-[4-(1,1,3,3-Tetramethylbutyl)phenoxy] ethoxy)ethanol Polyethylene Glycol Octylphenyl Ether;	9036-19-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)
115.		2-[4-(2,4,4-Trimethylpentan-2-yl)phenoxy]ethanol Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-Octylphenol ethoxylated	9002-93-1		Endocrine disrupting properties (REACH Article 57(f) – Environment)
116.		20-[4-(1,1,3,3-Tetramethylbutyl)phenoxy]-3,6,9,12,15,18-hexaoxaicosan-1-ol 3,6,9,12,15,18-Hexaoxaicosan-1-ol, 20-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-	2497-59-8	219-682-8	Endocrine disrupting properties (REACH Article 57(f) – Environment)
117.		Ethanol, 2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-	2315-67-5		Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
118.		Ethanol, 2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]-	2315-61-9		Endocrine disrupting properties (REACH Article 57(f) – Environment)
119.		3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-(4-octylphenoxy)-;	42173-90-0	255-695-5	Endocrine disrupting properties (REACH Article 57(f) – Environment)
120.		Poly(oxy-1,2-ethanediyl), α-(octylphenyl)-ω-hydroxy-, branched	68987-90-6		Endocrine disrupting properties (REACH Article 57(f) – Environment)
121.		Poly(oxy-1,2-ethanediyl), α-[4-(6-methylheptyl)phenyl]-ω-hydroxy-	59379-12-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)
122.		Ethanol, 2-(4-octylphenoxy)-; 2-(p-Octylphenoxy)ethanol	51437-89-9	257-203-4	Endocrine disrupting properties (REACH Article 57(f) – Environment)
123.		Poly(oxy-1,2-ethanediyl), α-(4-octylphenyl)-ω-hydroxy-	26636-32-8		Endocrine disrupting properties (REACH Article 57(f) – Environment)
124.		Poly(oxy-1,2-ethanediyl), α-[4-(1-methylheptyl)phenyl]-ω-hydroxy-	73935-42-9		Endocrine disrupting properties (REACH Article 57(f) – Environment)
125.		3,6,9,12,15,18-Hexaoxaicosan-1-ol, 20-(4-octylphenoxy)-; 20-(4-Octylphenoxy)-3,6,9,12,15,18-hexaoxaicosan-1-ol	32742-88-4	251-190-9	Endocrine disrupting properties (REACH Article 57(f) – Environment)
126.		Ethanol, 2-[2-[2-(4-octylphenoxy)ethoxy]ethoxy]ethoxy]-; 2-(p-Octylphenoxy)ethanol	51437-92-4		Endocrine disrupting properties (REACH Article 57(f) – Environment)
127.		Ethanol, 2-[2-(4-octylphenoxy)ethoxy]-	51437-90-2		Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
128.		3,6,9,12,15-Pentaoxaheptadecan-1-ol, 17-(4-octylphenoxy)-	51437-94-6		Endocrine disrupting properties (REACH Article 57(f) – Environment)
129.		Poly(oxy-1,2-ethanediyl), α-(isooctylphenyl)-ω-hydroxy-	9004-87-9		Endocrine disrupting properties (REACH Article 57(f) – Environment)
130.		2-[2-[2-(4-Octylphenoxy)ethoxy]ethoxy]ethanol	51437-91-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)
131.		3,6,9,12,15-Pentaoxaheptadecan-1-ol, 17-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-	2497-58-7		Endocrine disrupting properties (REACH Article 57(f) – Environment)
132.		Ethanol, 2-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethoxy]-	2315-62-0		Endocrine disrupting properties (REACH Article 57(f) – Environment)
133.		Ethanol, 2-[2-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethoxy]ethoxy]-	2315-63-1		Endocrine disrupting properties (REACH Article 57(f) – Environment)
134.		3,6,9,12-Tetraoxatetradecan-1-ol, 14-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-	2315-64-2		Endocrine disrupting properties (REACH Article 57(f) – Environment)
135.		3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-	2315-65-3		Endocrine disrupting properties (REACH Article 57(f) – Environment)
136.		3,6,9,12,15,18,21,24,27-Nonaoxanonacosan-1-ol, 29-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-	2315-66-4		Endocrine disrupting properties (REACH Article 57(f) – Environment)
137.		Ethanol, 2-[3-(1,1,3,3-tetramethylbutyl)phenoxy]-	1026254-24-9		Endocrine disrupting properties (REACH Article 57(f) – Environment)
138.		Ethanol, 2-[2-(1,1,3,3-tetramethylbutyl)phenoxy]-	84658-53-7		Endocrine disrupting properties (REACH Article 57(f) – Environment)

No	Name	EC names/Other names	CAS number	EC number	Classification/Other properties
139.		Ethanol, 2-[2-(octylphenoxy)ethoxy]-	27176-92-7		Endocrine disrupting properties (REACH Article 57(f) – Environment)
140.	N, N-Dimethylformamide	N, N-dimethylformamide; Dimethyl formamide, DMF	68-12-2	200-679-5	Toxic to reproduction cat.1B
141.	Prop-2-enamide	Acrylamide; 2-propenamide	79-06-1	201-173-7	Carcinogenic cat.1B/ Mutagenic cat.1B
142.	Pyridine, alkyl derivatives, with a content of $\geq 0,1$ % benzene (EC No 200-753-7)		68391-11-7	269-929-9	Carcinogenic cat.1A/ Mutagenic cat.1B
143.	Quinoline	Quinoline	91-22-5	202-051-6	Carcinogenic cat.1B
144.	Tetrahydrofurfuryl Alcohol	Tetrahydrofurfuryl alcohol; 2-Furanmethanol, tetrahydro-	97-99-4	202-625-6	Toxic to reproduction cat.1B ¹

⁽¹⁾ The limit for the acceptable presence of the substances listed in the table as unintentional impurity in the finished product is 0,1 % (weight by weight (w/w)) except where stated otherwise in this Annex.

⁽²⁾ The limit for the acceptable presence of this substance as unintentional impurity in the finished product is 0,01 % (weight by weight (w/w)), corresponding to the specific concentration limit set in Annex VI to Regulation (EC) No 1272/2008.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/384**of 3 March 2021****on the suitability of the denominations of varieties of agricultural plant species and vegetable species
and repealing Regulation (EC) No 637/2009****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species ⁽¹⁾, and in particular the second subparagraph of Article 9(6) thereof,

Having regard to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed ⁽²⁾, and in particular the second subparagraph of Article 9(6) thereof,

Whereas:

- (1) Directives 2002/53/EC and 2002/55/EC lay down general rules in relation to the suitability of variety denominations by means of a reference to Article 63 of Council Regulation (EC) No 2100/94 ⁽³⁾.
- (2) In accordance with Article 63 of Regulation (EC) No 2100/94 in order for a plant variety to be approved, its variety denomination needs to be considered suitable by the Community Plant Variety Office (CPVO). A variety denomination is suitable if there is no impediment in accordance with paragraphs 3 or 4 of that Article.
- (3) Commission Regulation (EC) No 637/2009 ⁽⁴⁾ establishes detailed rules for the application of certain criteria set out in Article 63 of Regulation (EC) No 2100/94 as to the suitability of denominations of varieties of agricultural species and vegetable plant species for purposes of the application of the first subparagraph of Article 9(6) of Directive 2002/53/EC and of the first subparagraph of Article 9(6) of Directive 2002/55/EC.
- (4) The CPVO and the Member States established an expert group, which developed and amended guidelines on the suitability of denominations under Article 63 of Regulation (EC) No 2100/94 ('Guidelines on variety denominations' ⁽⁵⁾). In order to ensure consistency as regards the application of the criteria provided for by Article 63 of Regulation (EC) No 2100/94, it is appropriate to provide for further clarifications resulting from the Guidelines on variety denominations.
- (5) Regulation (EC) No 637/2009 has been amended several times. In view of the need to amend the existing rules and in the interest of legal certainty, that Regulation should be repealed and replaced by this Regulation.
- (6) A variety denomination is to be approved, unless it is unsuitable due to impediments. Under Article 63 of Regulation (EC) No 2100/94 the use of a variety denomination is to be precluded in case of a prior right of a third party, difficulties as regards recognition or reproduction, identical denominations to a variety of the same or closely related species, designations commonly used for the marketing of goods, where the denomination is liable to give offence in one of the Member States or is contrary to public policy, in case of confusion due to visual, phonetical or conceptual similarity or of misleading content.

⁽¹⁾ OJ L 193, 20.7.2002, p. 1.

⁽²⁾ OJ L 193, 20.7.2002, p. 33.

⁽³⁾ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1).

⁽⁴⁾ Commission Regulation (EC) No 637/2009 of 22 July 2009 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species (OJ L 191, 23.7.2009, p. 10).

⁽⁵⁾ CPVO Guidelines on variety denominations, Meeting 1-of the Administrative Council of (2018), DOC-AC-2018-1-7.

- (7) In order to give sufficient time to competent authorities for the application of the new rules, this Regulation should apply from 1 January 2022.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes detailed rules for the application of the criteria set out in Article 63 of Regulation (EC) No 2100/94 as to the suitability of the denominations of varieties of agricultural plant species and vegetable species, for the purposes of the first subparagraph of Article 9(6) of Directive 2002/53/EC and of the first subparagraph of Article 9(6) of Directive 2002/55/EC.

Article 2

Suitability of variety denominations

1. A variety denomination shall be suitable, if there is no impediment related to its designation.
2. There is an impediment related to the designation of a variety denomination in cases where:
 - (a) the use of the variety denomination in the territory of the Union is precluded where an objection of a third party holding a prior right is upheld, as set out in Article 3(1);
 - (b) the variety denomination conflicts with geographical indications, designations of origin or traditional specialties guaranteed, as set out in Article 3(2);
 - (c) the variety denomination may cause its users difficulties as regards its recognition or reproduction, as set out in Article 4;
 - (d) the variety denomination is identical or may be confused with a variety denomination under which another variety of the same or of a closely related species is entered in an official register of plant varieties or under which material of another variety has been marketed, as set out in Article 5;
 - (e) the variety denomination could cause confusion due to its visual, phonetical or conceptual similarity with the denomination of a variety of the same or closely related species, as set out in Article 5;
 - (f) the variety denomination is identical or may be confused with designations commonly used for the marketing of goods, or which have to be kept free under other legislation, as set out in Article 6;
 - (g) the variety denomination is liable to mislead or to cause confusion, as set out in Article 7.

Article 3

Prior right of a third party

1. There is an impediment due to the prior right of a third party, where an objection of a third party, holding a trademark, against the designation of the variety denomination in the territory of the Union, is upheld by any competent authority. That impediment concerns trademarks which:
 - (a) have been registered in one or more Member States or in the Union before the registration of the variety denomination;
 - (b) are identical or similar to the variety denomination; and

(c) are registered in relation to goods consisting of the same or closely related species of the variety concerned.

2. In the case of geographical indications, designations of origin or traditional specialties guaranteed for agricultural products and foodstuffs, spirit drinks, aromatised wines and wine products as a prior right of a third party, a variety denomination in the territory of the Union shall be precluded where the variety denomination would breach:

(a) Article 13 or 24 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council ⁽⁶⁾;

(b) Article 103 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽⁷⁾;

(c) Article 20 of Regulation (EU) No 251/2014 of the European Parliament and of the Council ⁽⁸⁾;

(d) Article 21(2) of Regulation (EU) 2019/787 of the European Parliament and of the Council ⁽⁹⁾.

3. An impediment to the suitability of a denomination due to the prior right referred to in paragraph 1 shall cease to exist where a written consent of the holder of the prior right to the use of the denomination in relation to the concerned variety has been obtained, provided that such a consent is not liable to mislead the public as to the true origin of the product.

4. In the case of a prior right of the applicant in respect of the whole or part of the proposed variety denomination, Article 18(1) of Regulation (EC) No 2100/94 shall apply *mutatis mutandis*.

Article 4

Difficulties as regards recognition or reproduction of a variety denomination

1. There is an impediment due to difficulties as regards recognition or reproduction of a variety denomination where a variety denomination causes its users difficulties as regards its recognition or reproduction.

2. It shall be considered that a variety denomination causes its users difficulties as regards its recognition or reproduction in the following cases:

(a) it consists of, or contains, comparatives or superlatives;

(b) it consists of, or contains, botanical names of species within the group either of agricultural plant species or of vegetable plant species, to which the variety belongs;

(c) it consists of, or contains, breeding and technical terms, unless their use in combination with other terms would not prevent the recognition of the variety denomination as such;

(d) it consists exclusively of a geographical name that has acquired a reputation for the species concerned;

(e) it consists of a single letter or numeral or numerals only, unless this represents an established practice for designating certain varieties;

⁽⁶⁾ Regulation (EU) No 1151/2012 of the European Parliament and the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (OJ L 343, 14.12.2012, p. 1).

⁽⁷⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽⁸⁾ Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No 1601/91 (OJ L 84, 20.3.2014, p. 14).

⁽⁹⁾ Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 (OJ L 130, 17.5.2019, p. 1).

- (f) it consists of, or contains, too many words or elements, unless the flow of the wording makes it easily recognizable;
- (g) it contains a punctuation mark or other symbol, an upper and lower case mixture (except where the first letter is in upper case and the rest of the denomination in lower case), subscript, superscript or a design or a figurative element (except the apostrophe (')), the comma (,), up to two non-adjacent exclamation marks (!), the period or full-stop (.), or the hyphen (-), the forward slash (/) or backward slash (\) symbols);
- (h) it contains, or consists of, a subscript, a superscript or a design, a logo or a figurative element.

Article 5

Denomination that is identical or may be confused with the denomination of another variety

1. There is an impediment for the designation of a variety denomination where it is identical or may be confused with:
 - (a) a variety denomination under which another variety of the same or a closely related species is entered in an official register of varieties; or
 - (b) a variety denomination under which material of another variety has been marketed in a Member State or in the territory of a contracting party of the International Union for the Protection of New Varieties of Plants (UPOV);

unless the other variety no longer remains in existence and its denomination has acquired no special significance.

2. In order to establish whether there is a confusion for the purposes of paragraph 1, the competent authority shall first analyse each of the visual, phonetical and conceptual aspects separately and then make an overall assessment, taking also into account denominations of varieties of the same or a closely related species, provided that the varieties concerned referred to in this paragraph and in paragraph 1 have been either the subject of a plant variety right or of an application thereof, or officially accepted for marketing, in the territory of one of the following:

- (a) the Union;
- (b) the European Economic Area;
- (c) a contracting party of the UPOV;
- (d) a Member of the Organisation for Economic Cooperation and Development (OECD).

3. For the purposes of this Article, the following definitions apply:

- (a) 'closely related species' means the species listed in the Annex;
- (b) 'official register of varieties' means the Common catalogue of Varieties of Agricultural Plant Species, referred to in Article 17 of Directive 2002/53/EC or in Article 17 of Directive 2002/55/EC, or the OECD Variety List, or a plant variety register of a Member of UPOV;
- (c) 'a variety no longer remains in existence' means a variety of which material no longer exists;
- (d) 'the denomination has acquired no special significance' means a situation where the denomination of a variety which has been entered in an official register of varieties is considered to have lost special significance on the expiry of a 10-year period after deletion from that register, unless there are exceptional circumstances.

Article 6

Designations commonly used for the marketing of goods

1. There is an impediment to the designation of a variety denomination where a variety denomination is identical or may be confused with designations which are commonly used for the marketing of goods or which have to be kept free under other legislation.

2. Designations which are commonly used for the marketing of goods or which have to be kept free under other legislation shall be:

- (a) currency denominations;
- (b) terms associated with weights and measures;
- (c) expressions and terms that are not to be used for other purposes than those envisaged by the legislation of the Union or of a Member State.

Article 7

Misleading content

1. There is an impediment for the designation of a variety denomination where it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder or of any other party to the proceedings.

2. It shall be considered that a variety denomination is liable to mislead or to cause confusion if:

- (a) it conveys a false impression that the variety is related to, or derived from, another specific variety;
- (b) it conveys a false impression that the variety has a particular characteristic or value;
- (c) it refers to a specific characteristic or value in a way which conveys a false impression that only that variety possesses that specific characteristic or value, whereas other varieties of the same species may possess the same characteristic or value;
- (d) it is similar to a well-known trading name other than a registered trademark or variety denomination;
- (e) it suggests that the variety is another variety;
- (f) it conveys a false impression concerning the identity of the applicant, the person responsible for the maintenance of the variety or the breeder;
- (g) it consists of, or contains:
 - (i) comparatives or superlatives which may be deceptive as to the characteristics of the variety;
 - (ii) the botanical or common names of species, within the group either of agricultural plant species or of vegetable plant species, to which the variety belongs;
 - (iii) the name of a natural or legal person, or a reference thereto, so as to convey a false impression concerning the identity of the applicant, the person responsible for the maintenance of the variety or the breeder;
- (h) it includes a geographical name that is likely to deceive the user as to the characteristics or the value for cultivation and use of the variety.

Article 8

Repeal of Regulation (EC) No 637/2009

Regulation (EC) No 637/2009 is repealed.

However, it shall continue to apply to variety denominations which have been proposed by the applicant to the competent authority for their approval before 1 January 2022.

Article 9

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Definition of closely related species within the meaning of Article 5(3)

For the purpose of defining 'closely related species', as referred to in Article 5(3), the following shall apply:

- (a) if there is more than one class within a genus, the list of classes in part I shall apply;
- (b) if classes encompass more than one genus, the list of classes in part II shall apply;
- (c) as a general rule, for genera and species not covered by the lists of classes in parts I and II, a genus is considered to be a class.

PART I

CLASSES WITHIN A GENUS

Classes	Botanical names
Class 1.1:	<i>Brassica oleracea</i>
Class 1.2:	<i>Brassica</i> other than <i>Brassica oleracea</i>
Class 2.1:	<i>Beta vulgaris</i> L. var. <i>alba</i> DC., <i>Beta vulgaris</i> L. var. <i>altissima</i>
Class 2.2:	<i>Beta vulgaris</i> ssp. <i>vulgaris</i> var. <i>conditiva</i> Alef. (syn.: <i>B. vulgaris</i> L. var. <i>rubra</i> L.), <i>B. vulgaris</i> L. var. <i>cicla</i> L., <i>B. vulgaris</i> L. ssp. <i>vulgaris</i> var. <i>vulgaris</i> .
Class 2.3:	<i>Beta</i> other than classes 2.1 and 2.2.
Class 3.1:	<i>Cucumis sativus</i>
Class 3.2:	<i>Cucumis melo</i>
Class 3.3:	<i>Cucumis</i> other than classes 3.1 and 3.2
Class 4.1:	<i>Solanum tuberosum</i> L.
Class 4.2:	Tomato & Tomato rootstocks: — <i>Solanum lycopersicum</i> L. (<i>Lycopersicon esculentum</i> Mill.) — <i>Solanum cheesmaniae</i> (L. Ridley) Fosberg (<i>Lycopersicon cheesmaniae</i> L. Riley) — <i>Solanum chilense</i> (Dunal) Reiche (<i>Lycopersicon chilense</i> Dunal) — <i>Solanum chmielewskii</i> (C.M. Rick et al.) D.M. Spooner et al. (<i>Lycopersicon chmielewskii</i> C. M. Rick et al.) — <i>Solanum galapagense</i> S.C. Darwin & Peralta (<i>Lycopersicon cheesmaniae</i> f. <i>minor</i> (Hook. f.) C. H. Müll.) (<i>Lycopersicon cheesmaniae</i> var. <i>minor</i> (Hook. f.) D. M. Porter) — <i>Solanum habrochaites</i> S. Knapp & D.M. Spooner (<i>Lycopersicon agrimoniifolium</i> Dunal) (<i>Lycopersicon hirsutum</i> Dunal) (<i>Lycopersicon hirsutum</i> f. <i>glabratum</i> C. H. Müll.) — <i>Solanum pennellii</i> Correll (<i>Lycopersicon pennellii</i> (Correll) D'Arcy) — <i>Solanum peruvianum</i> L. (<i>Lycopersicon dentatum</i> Dunal) (<i>Lycopersicon peruvianum</i> (L.) Mill.) — <i>Solanum pimpinellifolium</i> L. (<i>Lycopersicon pimpinellifolium</i> (L.) Mill.) (<i>Lycopersicon racemigerum</i> Lange) and hybrids between those species
Class 4.3:	<i>Solanum melongena</i> L.
Class 4.4:	<i>Solanum</i> other than classes 4.1, 4.2 and 4.3

PART II

CLASSES ENCOMPASSING MORE THAN ONE GENUS

Classes	Botanical names
Class 201:	<i>Secale</i> , <i>Triticosecale</i> , <i>Triticum</i>
Class 203 *:	<i>Agrostis</i> , <i>Dactylis</i> , <i>Festuca</i> , <i>Festulolium</i> , <i>Lolium</i> , <i>Phalaris</i> , <i>Phleum</i> and <i>Poa</i>
Class 204 *	<i>Lotus</i> , <i>Medicago</i> , <i>Ornithopus</i> , <i>Onobrychis</i> , <i>Trifolium</i>
Class 205:	<i>Cichorium</i> , <i>Lactuca</i>

* Classes 203 and 204 are not solely established on the basis of closely related species

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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