

CLARIFICATION OF ARTICLE 5 OF THE ROYAL DECREE OF 5 FEBRUARY 2016

Article 5 of the Royal Decree of 5 February 2016 on the manufacture and placing on the market of tobacco products and herbal smoking products regulates the composition of tobacco-based products.

Paragraph 3, 4° reads as follows:

*“It is forbidden to market tobacco-based products containing the following additives:
4° with respect to tobacco-based products intended for smoking, all additives facilitating nicotine inhalation or intake;”*

The FPS Health wants to clarify this prohibition. Based on scientific evidence, expert opinions and international consultations, all components and mixtures with cooling and/or analgesic effects are considered as facilitating inhalation.

In order to illustrate this principle, a list has been made with examples of components forming part of this prohibition. Menthol and geraniol are the best-known examples. That list is not restrictive and can be adapted on the basis of progressive insight. Please find the list attached.

This prohibition applies to cigarettes, hand-rolling tobacco, cigars, cigarillos, pipe tobacco, water-pipe tobacco and novel tobacco-based products.

IN PRACTICE

This prohibition implies:

- that tobacco products for smoking that contain a component with cooling and/or analgesic effects are not authorized on the Belgian market;
- that from 1 March 2022 onwards, for all notifications of tobacco-based products for smoking that are submitted via the EU-CEG, the list of ingredients shall not contain any of those components.

Manufacturers and/or importers are asked to withdraw from the market any cigarettes, hand-rolling tobacco, cigars, cigarillos, pipe tobacco, water-pipe tobacco and novel tobacco-based products containing said components.

The competent services will perform checks as of 2022.

In case you have questions, please contact enottab@health.fgov.be

ANNEX

Examples of prohibited additives in tobacco products for smoking in application of the Royal Decree of 5 February 2016, Article 5. §3, 4°.

These include, among others, all the TRPM8 thermoreceptor activators.

Name	Other names	FEMA/CAS non-exhaustive
Menthol and analogues of natural origin, including:		
Menthol		CAS 1490-04-6, 89-78-1
(-) menthol		CAS 2216-51-5
(+)-menthol		CAS 15356-60-2
Menthon		CAS 1490-04-6
(-)-menthon		CAS 2216-51-5
(+)-menthon		CAS 15356-60-2
p-menthane-3,8-diol	PMD38, Coolact 38D	FEMA-4053; CAS 42822-86-6, CAS 91739-72-9
1,8-cineole	eucalyptol	FEMA-2465; CAS 470-82-6
1,4-cineole		FEMA-3658; CAS 470-67-7
Mentha: oil or parts of plant		FEMA-2848, 3032; CAS 8006-90-4, 8008-79-5, 68606-97-3, 84696-51-5, 8008-79-5
Eucalyptus: oil or parts of plant		FEMA-2466; CAS 8000-48-4
Ocimum: oil or parts of plant		FEMA-2118, CAS 8015-73-4
Thymus: oil or parts of plant		FEMA-3063, 3064; CAS 84929-51-1, 8007-46-3
Salvia: oil or parts of plant		FEMA-3001; CAS 8022-56-8
Mono-terpenes		
Geraniol		CAS 106-24-1
(-)-isopulegol	Coolact P	FEMA-2962; CAS 89-79-2, 7786-67-6
L-carvone		CAS 6485-40-1
Hydroxy-citronellal		CAS 107-75-5
Linalool		CAS 78-70-6
Synthetic coolants		
Ester derivatives of menthol, including:		
Menthyl lactate	Frescolat ML	FEMA-3748; CAS 61597-98-6
Monomenthyl succinate		FEMA-3810; CAS 77341-67-4

Menthyl-3-hydroxybutyrate		FEMA-4308; CAS 108766-16-1, 115869-76-6
Menthyl acetate		FEMA-2668; CAS 89-48-5, 2623-23-6, 16409-45-3
Menthol ethylene glycol carbonate	Frescolat MGC	FEMA-3805; CAS 156324-78-6
WS-30	2,3-dihydroxypropyl p-menthane-3-carboxylate	
Ether derivatives of menthol, including:		
Menthoxypropane-1,2-diol	MPD, Coolact-10	FEMA-3784; CAS 207792-35-6, 87061-04-9
Amide derivatives of menthol, including:		
WS-3	N-ethyl-p-menthane-3-carboxamide	FEMA-3455; CAS 39711-79-0
WS-5	(1R,2S,5R)-N-((ethoxycarbonyl)methyl)-p-menthane-3-carboxamide	FEMA-4309, CAS 68489-14-5
WS-12	CPS-112, (1R,2S,5R)-N-(4-methoxyphenyl)-p-menthane-3-carboxamide	FEMA-4681, CAS 68489-09-8
WS-14	N-tert-butyl-p-menthane-3-carboxamide	
WS-23	2-isopropyl-N,2,3-trimethylbutyramide	FEMA-3804, CAS 51115-67-4
WS-109	CPS-369, N-(p-menthane-3-carbonyl)-D-alanine ethyl ester	
CPS-124	N-(4-fluorophenyl)-p-menthane-3-carboxamide	
CPS-125		
CPS-128	N-(4-ethoxyphenyl)-p-menthane-3-carboxamide	
CPS-368		
Ketal derivatives of menthol, including		
Menthon-1,2-glycerol ketal	Frescolat MGA	CAS 63187-91-7
Others		
Icilin, including all derivatives		CAS 36945-98-9
5-methyl-4-(1-pyrrolidinyl)-3-2H-furanone		
WS-148	CPS-148, 1-(di-sec-butyl-phosphinoyl)-heptan	