

SPAIN

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14. SPAIN**PETROLEUM WAXES**
NATURAL ESTER WAXES

USAGE : **In/on food** - As component, coating or surface treatment

REGULATIONS

(a) General food regulations concerning food components and food contact materials :

1. Presidential Decree (P.D.) 2484/67 amended by Royal Decree (R.D.) 1330/85 published in Boletín Oficial de Estado (B.O.E.) 16 December 1985.
2. P.D. 2519/74 of 9 August 1974. Since the publication of this P.D. the following amendments have been introduced :

R.D. 336/75	B.O.E. 11 March 1975
R.D. 2688/76	B.O.E. 26 November 1976
R.D. 3452/77	B.O.E. 24 January 1978
R.D. 1597/82	B.O.E. 23 July 1982
R.D. 2058/82	B.O.E. 30 August 1982
R.D. 1353/83	B.O.E. 27 May 1983
R.D. 1998/83	B.O.E. 29 July 1983
R.D. 106/85	B.O.E. 31 January 1985
R.D. 841/85	B.O.E. 7 June 1985
R.D. 842/85	B.O.E. 7 June 1985
R.D. 503/86	B.O.E. 14 March 1986
R.D. 504/86	B.O.E. 14 March 1986

3. Decision dated 12 June 1975 regarding the Special Register of Food Industries.
4. Decision No. 763 of the Vice-Secretary for Health dated 12 December 1977 regarding the Food Sectors of the Health Register of Foodstuffs and Food Industries (published in B.O.E. 12 January 1978).
5. R.D. 1712/91 regarding Health Register of Foodstuffs published in B.O.E. 4 December 1991.
6. R.D. 2825/81 regarding documentation for registering a material as food additive.
7. R.D. 2688/77 dated 23 July 1977, amending Decree 335/1955 of 7 March 1955 and Home Ministry Order dated 18 August 1975 regarding the registration numbers of foodstuffs.

(b) Regulations specific for certain foods :

1. Bread and special breads - Decree 338/1975 dated 7 March 1975.
2. Marzipan, bon-bons and confectionery : Resolution 3852 dated 16 December 1975 (published in B.O.E. dated 20 February 1976). This Resolution refers to the positive list of additives permitted for marzipans and bon-bons. Later amended by R.D. 1167/90 (B.O.E. 26 September 1990).
3. Chewing gum : R.D. 1810/91 (B.O.E. 25 December 1991).

GENERAL TERMS OF REGULATIONS

In general companies wishing to market materials for use in/on food or in contact with food must proceed through a registration formality under Spanish regulations, namely :

The company marketing the products, whether it manufactures them or not, must apply to the authorities for inclusion on the Food Industry Register. For this purpose details of the company, its installations, activities and the products involved have to be submitted.

Regulations (a) 1.-7. above control these general aspects.

There are no official Spanish regulations which specifically control the general use of waxes in/on foods; however regulations relating to particular types of foodstuff mention waxes in certain instances :

- Breads and special breads : Regulation (b) 1. permits the use of spermaceti and beeswax as components of mould release aids in the production of these foods.
- Marzipan, bon-bons, confectionery and chewing gum : Regulation (b) 2. gives a positive list of additives approved for use as components of these; the list includes :
 - . paraffin wax
 - . microcrystalline wax
 - . candelilla wax
 - . carnauba wax
 - . beeswax.

The positive list is the one contained in the Resolution 3853 published in B.O.E. 20 February 1976 later amended by Resolution published in B.O.E. 16 October 1979 and B.O.E. 13 September 1982 as well as Ordén 248/85 published in B.O.E. 27 October 1988.

No quality requirements are specified, nor the concentrations which are permitted.

- Cheese, citrus fruits : There are no specific Spanish Governmental regulations relating to use of waxes for cheese coating or for treating the skin of citrus fruits.

14. SPAIN**PETROLEUM WAXES
SYNTHETIC HYDROCARBON WAXES
NATURAL ESTER WAXES**

USAGE : **In contact with food** - In/on food packaging materials

REGULATIONS

- (a) General food regulations : Regulations quoted under (a) 1, 2, 3, 4, 5 and 7 of page 14.1.
- (b) R.D. 2825/81 regarding documentation for registering a material as food additive.
- (c) Use of plastics in contact with foodstuffs :
 1. Royal Decree 2686/1976 of 10 October 1976 (gave approval for regulations governing this usage).
 2. Resolution 30787 (B.O.E. 24 November 1982) amended by R.D. 2814/83 and Orden 14157 (B.O.E. 12 July 1985).

GENERAL TERMS OF REGULATIONS

Registration of products sold for use in contact with food, and also of the company marketing them, are required under Spanish regulations as described for the usage "In/on food" - Regulations (a) 1. to 7., pages 14.1 and 14.2.

There are no official Spanish regulations which specifically control the use of waxes in applications involving contact with food. However regulation (c) 2. gives a positive list of components permitted for plastics intended to contact foods, and this includes the following waxes :

- . natural ester waxes (carnauba, candelilla, beeswax, Japan wax)
- . polyethylene wax
- . refined ceresin
- . spermaceti
- . refined montan wax
- . microcrystalline paraffin wax
- . hard paraffins (including synthetic paraffins).

This regulation also contains a list of maximum migration limits for individual additives in polymeric materials in contact with food, but this list does not mention migration limits for waxes.

14. SPAIN**NATURAL ESTER WAXES**

USAGE : **Pharmacy**

REGULATIONS

The European Pharmacopoeia, 2nd Edition, includes monographs for white beeswax and yellow beeswax; for details refer to Section 19 - European Economic Community - as at August 1987 these are the only sections on waxes in the European Pharmacopoeia although it is understood that a monograph on carnauba wax is to be issued.

The Pharmacopoeia requirements for beeswax in all countries adopting the European Pharmacopoeia are therefore now identical and as given in Section 19; these requirements supersede those of the individual national pharmacopoeias.

It is understood that the following countries have agreed to adopt the requirements of the European Pharmacopoeia, either as original parties to the Convention on the Elaboration of a European Pharmacopoeia or through subsequent decisions (the European Pharmacopoeia has official status in the laws of the European Economic Community) :

Austria
Belgium
Denmark
EIRE
Finland
France

Germany
Greece
Italy
Luxembourg
Netherlands
Norway

Portugal
Spain
Sweden
Switzerland
United Kingdom