

SWEDEN**INDEX**

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15. SWEDEN**PARAFFIN WAX
NATURAL ESTER WAXES
PETROLATUMS**

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

REGULATIONS

- (a) The Food Act dated 18 June 1971 (SFS 1971:511) and subsequent amendments.
- (b) The Food Decree dated 5 November 1971 (SFS 1971:807) and subsequent amendments.
- (c) The National Food Administration's Ordinances on Food Additives :
 1. SLV 1975:11 dated 3 June 1975 and its Appendix, List of Food Additives 1976.
 2. SLV FS 1977:6 : Changes in the Ordinance SLV 1975:11 on Food Additives - and its Appendix, the 1977 List of Food Additives, Part 3, changes in relation with the 1976 list.

(The List of Food Additives is issued annually. However it is understood that, as of May 1980, no amendments have been made to the 1977 list.)

GENERAL TERMS OF REGULATIONS

Under the terms of regulations (a) and (b) rules relating to food additives are given in (c). Regulation (c) lists the additives permitted in various foods. The purpose for which the additive may be used is specified for each, and in many instances maximum concentration limits are set. Regulations (a) and (c) clearly state that it is forbidden to sell food containing food additives other than those currently approved by the authorities and meeting the regulations.

Regulation (b) states in its § 3 (which is modified by (c) 1. and 2.) that certain food additives are exempted from the requirement that additives should be approved. Such exempted materials are defined as :

"... products or substances which are not colours and which have been obtained from animals or plants by drying, heat-treatment, extraction with water or by purely mechanical treatment, common salt or sugars, vinegar, diluted acetic acid or ethyl alcohol, non-toxic essences or flavourings used to impart a specific odour or taste.

The exemption does not apply to smoke flavours (smoke extracts)."

Food groups in which such exempted additives may be used are indicated in the List of Food Additives along with the purpose of the addition.

Presumably the natural ester waxes such as beeswax, carnauba wax, spermaceti, etc. would fall within the above definition.

The provisions of regulations (c) 1. and 2. in relation to uses of waxes and petrolatums in/on food are summarised below.

| Usage | Waxes permitted (or other note where appropriate) | Max. concentration limit (where specified) |
|---|---|---|
| Chocolate and Confectionery | Paraffin wax. | 5 g/kg (for surface treatment only) |
| - surface treatment agents | Soft paraffin (i.e. petrolatum) - for surface treatment. | 5 g/kg |
| - (chewing gum) | Soft paraffin (i.e. petrolatum) - for chewing gum only. Chewing gum is included under "Chocolate and Confectionery" for which "exempted" additives are permitted under § 3 of the Food Decree (see note above). This presumably permits natural ester waxes to be used for the above purposes where appropriate. There is no mention of the use of waxes as components of chewing-gum. | 6 g/kg |
| Fresh fruit (unpeeled citrus fruits) | There is no direct mention of wax of any type being permitted for this usage, however "exempted" additives under § 3 of the Food Decree are allowed (see note above). | None specified. |
| - surface protecting agents | There is no mention of cheese coatings, only of surface treatment (with preservatives). | None specified. |
| Cheese | However once again exempted additives are permitted to be used in/on cheese under § 3 of the Food Decree (see note above). | None specified. |
| - coating | | |

References (c) 1. and 2. include a list of additives grouped according to their function; in this paraffin wax and soft paraffin (i.e. petrolatum) appear as "surface treatment agents".

Antioxidants : The following are included in the list of additives under "Antioxidants and Antioxidant Synergists", and the regulations permit their use in particular types of food :

- Butylated hydroxyanisole (BHA)
- Butylated hydroxytoluene (BHT)
- Tocopherol and Tocopherol concentrate.

Labelling requirements : References (c) 1. and 2. give the statutory requirements for labelling of packages holding food additives or foods containing additives.

QUALITY REQUIREMENTS

Reference (c) states that food additives shall be of a standard of purity appropriate for use in food, and that if the Food and Agriculture Organisation of the United Nations and the World Health Organisation have issued recommendations for the purity of a particular additive, then these standards must be met.

The FAO/WHO have not yet (*) issued any recommendations with regard to purity of waxes and petrolatums used in/on food, so that in effect there are no specific quality requirements for such usage in Sweden but only the general requirement for "appropriate purity".

(*) April 1981.

15. SWEDEN**GENERAL REQUIREMENTS**

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

REGULATIONS

The Swedish legislation does not contain any detailed requirements for food packaging materials, but general requirements for food packaging are indicated in :

- (a) The Food Act dated 18 June 1971 (SFS 1971:511) and subsequent amendments.
- (b) The Food Decree dated 5 November 1971 (SFS 1971:807) and subsequent amendments.

GENERAL TERMS OF REGULATIONS

Although no specific requirements are made regarding packaging materials the following general principles must be met.

Regulation (a) § 8 states that "in the handling of food every precaution shall be taken to ensure that the food runs no risk of being contaminated or unfit for human consumption", and handling is defined (§ 2) as including packing and re-packing of food.

Regulation (b) § 7 states that "food packaging materials... may not be of such a character that, when in use, there is a risk of the food being exposed to foreign substances, contaminated or made unfit for human consumption". Also § 8 states that "It is specially to be observed that food shall be kept properly separated from substances which are injurious to health".

Advice received from the National Food Administration in Uppsala indicates that the authorities tend to follow the statutory regulations in other countries in considering questions concerning food packaging materials; in particular the regulations issued by the US Food and Drug Administration, the German Bundesgesundheitsamt and the Netherlands authorities appear to be taken into consideration.

15. SWEDEN**PARAFFIN WAX
NATURAL ESTER WAXES
PETROLATUMS**

USAGE : Pharmacy

REGULATIONS : With regard to waxes and petrolatums the Pharmacopoeia Nordica applies.

GENERAL REQUIREMENTS OF REGULATIONS

The Pharmacopoeia has sections on the following :

- a) Paraffinum solidum (hard paraffin)
- b) Cera alba (white beeswax)
- c) Cera flava (yellow beeswax)
- d) Cetaceum (spermaceti)
- e) Vaselinum (yellow petrolatum)
- f) Vaselinum album (white petrolatum)

For details of the requirements for the above materials, see Section 3 - Denmark.

15. SWEDEN**NATURAL ESTER WAXES
(ADDENDUM)**

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