

**SUBSIDIARY LEGISLATION 231.41****EXTRACTION SOLVENTS FOR FOODSTUFFS  
REGULATIONS**

27th April, 1999

*Legal Notice 25 of 1999.*

**1.1** The title of these Regulations is Extraction Solvents for Foodstuffs Regulations. Title.

**2.1** In these regulations, the following definitions shall apply, unless the context otherwise requires - Interpretation.

"solvent" means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff; and

"extraction solvent" means a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of such products and which is removed but which may result in the unintentional but technically unavoidable presence of residues or derivatives in the foodstuff or food ingredient.

**3.1** Only the substances and materials permitted by these regulations may be used as extraction solvents in the processing of raw materials, foodstuffs, food components or food ingredients and only under the specified conditions of use and within the maximum residue limits, if any. Permitted list of extraction solvents.

**3.2** The following extraction solvents are permitted for all uses, in accordance with good manufacturing practice provided that any resulting residues or derivatives are present only in technically unavoidable quantities presenting no danger to human health:

Propane	Acetone*
Butane	Nitrous oxide
Ethyl acetate	Carbon.
Ethanol	

**3.3** The following extraction solvents may be used only under the specified conditions of use:

Name/condition of use (summary description of extraction)	Maximum residue limits in extracted foodstuff or food ingredient
Hexane <sup>2</sup> (A commercial product consisting essentially of acyclic saturated hydrocarbons containing 6 carbon atoms and distilling between 64°C and 70°C)	

\*The use of acetone in the refining of olive pomace oil is prohibited.

Name/condition of use (summary description of extraction)	Maximum residue limits in extracted foodstuff or food ingredient
Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in fat or oil or cocoa butter
Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and defatted flours 30 mg/kg in the defatted soya products as sold to final consumer
Preparation of defatted cereal germs	5 mg/kg in defatted cereal germs
Methyle acetate	
Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in coffee or tea
Production of sugar from molasses	1 mg/kg in sugar
Ethyl methyl ketone <sup>3</sup>	
Fractionation of fats and oils	5 mg/kg in fat or oil
Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in coffee or tea
Dichloromethane	
Decaffeination of, or removal of irritants and bitterings from coffee and tea	2 mg/kg in roasted coffee, 5 mg/kg in tea
Methanol	
All uses	10 mg/kg
Propan-2 ol	
All uses	10 mg/kg

2 The combined use of hexane and ethyl methyl ketone is prohibited.

3.4 The following extraction solvents may be used only under the specified of use:

Name	Maximum residue limits in foodstuffs due to use of extraction solvents in preparation of flavourings from natural flavouring materials
Diethyl ether	2 mg/kg
Hexane <sup>3</sup>	1 mg/kg
Cyclohexane	1 mg/kg
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethyl methyl ketone <sup>3</sup>	1 mg/kg
Dichloromethane	0.02 mg/kg
Propan-1-ol	1 mg/kg
1, 1, 1, 2-tetrafluoroethane	0.02 mg/kg

3 The presence of n-hexane in this solvent should not exceed 50 mg/kg. This solvent may not be used in combination with hexane.

3.5 The use as solvents for the extraction of flavourings from natural flavouring materials of substances used for diluting or dissolving flavourings is allowed. Additional authorisations.

3.6 Water, to which substances regulating acidity or alkalinity may have been added, other foodstuffs with solvent properties and ethanol are authorised as extraction solvents in the manufacture of foodstuffs or food ingredients.

4.1 These regulations shall apply to extraction solvents used or intended for use in the production of foodstuffs or food ingredients. Applicability.

4.2 These regulations shall apply without prejudice to provisions adopted under more specific regulations.

4.3 These regulations shall apply equally to foodstuffs or food ingredients imported into Malta, in the production of which extraction solvents have been used.

4.4 These regulations shall not apply to extraction solvents or to foodstuffs intended for export from Malta.

4.5 These regulations shall not apply to extraction solvents used in the production of food additives, vitamins and other nutrients unless these are listed in regulations 3.2, 3.3 or 3.4 and provided that the use of food additives, vitamins and other nutrients does not result in foodstuffs containing extraction solvent residue levels which are dangerous to human health.

5.1 The substances listed in regulations 3.2, 3.3 and 3.4 and which are intended for use as extraction solvents in foodstuffs may only be marketed if their packaging, labels or containers carry the following information which must be clearly visible, legible and indelible: Labelling.

5.1.1 the commercial name of the substance as listed in regulations 3.2, 3.3 and 3.4;

5.1.2 a clear indication that the material is of a quality suitable for use for the extraction of food or food ingredients;

5.1.3 an identifying batch or lot reference;

5.1.4 the name or business name and address of the manufacturer, packer or of a seller established in Malta;

5.1.5 the net quantity, in units of volume;

5.1.6 if necessary, any special storage conditions or conditions of use.

5.2 The information specified in regulations 5.1.3, 5.1.4, 5.1.5 and 5.1.6 may appear only on the trade documents relating to the batch or lot which are to be supplied with or prior to the delivery.

5.3 The provisions laid down in this regulation shall apply without prejudice to more precise or more extensive provisions regarding weights and measures or provisions applying to the classification, packing and labelling of dangerous substances and preparations.

5.4 The particulars provided for in this regulation shall appear in Maltese, English or Italian. This provision shall not prevent such

particulars from being additionally indicated in other languages.

Purity criteria.

**6.1** The substances and materials listed as extraction solvents in regulations 3.2, 3.3 and 3.4 shall not contain a toxicologically dangerous amount of any element or substance and, unless specific purity criteria determine otherwise, shall not contain more than 1 mg/kg of arsenic or more than 1 mg/kg of lead.

Danger to health.

**6.2** The Superintendent of Public Health may temporarily suspend or restrict the use of any extraction solvent if there are detailed grounds for establishing that the use in any foodstuff of the substance or the level of one or more of the solvent's components might endanger human health.

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