

Technical and product data for vegetable and essential oil EU compliance



ABioSA GUIDE

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**forestry, fisheries
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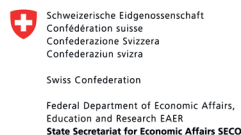
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Introduction

This ABioSA guide is for SMEs who need to create a Technical Data Sheet (TDS) and Product Data Sheet (PDS) for a product or raw material based on vegetable or essential oils.

The information listed in a TDS or PDS can help an importer, retailer, consumer or any user of the product to understand the quality, safety and regulatory obligations of the product.

It provides the information necessary for cosmetic product formulators, producers and safety assessors; and inspires overall confidence in the product.

Glossary

- **CAS** - Chemical Abstract Service, a division of the American Chemical Society
- **CMR** - EU cosmetics legislation contains provisions for the use of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR substances) in cosmetic products. In general, the use of CMR substances is prohibited, apart from in exceptional cases.
- **GLP** - Good Laboratory Practice
- **GMO** - Genetically Modified Organism
- **GMP** - Good Manufacturing Practice
- **EC number** - The European Commission number is a numerical classification for enzymes, based on the chemical reactions they catalyse
- **Essential oil** - an essential oil is the volatile part of a natural product, which can be obtained by distillation, steam distillation or expression in the case of citrus fruits. It contains mostly volatile hydrocarbons. The oil is 'essential' in the sense that it carries a distinct scent, or essence of the plant.
- **INCI** - International Nomenclature of Cosmetic Ingredients
- **PDS** - Product Data Sheet
- **PIF** - Product Information File
- **PIS** - Product Information Sheet (another name for a Product Data Sheet)
- **REACH** - Registration, evaluation, authorisation, and restriction of chemicals
- **TDS** - Technical Data Sheet
- **Vegetable oil** - Vegetable fats and oils are substances generally obtained from the seeds of plants, although some other parts of the plants may also yield oils. Vegetable oils and fats are mainly composed of triglycerides, which contain a range of fatty acids of different chain lengths.

Technical Data Sheet (TDS)

A TDS is a summary of the physical, chemical and other information related to a product or substance. It is also known as a Specification Sheet.

The TDS should include the specific value or range of values acceptable for a product across multiple parameters, and how it was measured.

Typical information on a Technical Data Sheet

	Seed or vegetable oil	Essential oil
General information		
Chemical and botanical name, CAS number if available, INCI name, etc.	x	x
General description of the product or oil, including origin and production, extraction process, overall composition etc.	x	x
Pictures of the final product	optional	optional
Physical and chemical data and technical information		
Appearance	x	x
Odour	x	x
Peroxide value	x	x
Acid value	x	x
Density	x	x
Refractive index	x	x
Solubility	x	x
Viscosity	x	x
Additional information on the performance of the product	x	x
Chemical composition		
Fatty acid composition - main components	x	
Main components - analysed by a gas chromatographic (GC) profile		x
Additional information		
Shelf life	x	x
Stability	x	x
Typical uses	x	x
Handling	x	x
Packaging and storage	x	x

General information

General identification

The identification of the product should be provided, including the family, genus, species and variety or cultivar of the plant it comes from. The chemical name, CAS number, EC number and INCI name of the product, raw material or oil should be stated (if available).

General description of the product

The identification should include the country where the product or substance originated and a brief description of its composition and the manufacturing or extraction process.

Pictures of the product

Pictures of the product or ingredients are optional, but will give the customer an idea of what it should typically look like.

Physical and chemical data and technical information

The TDS contains information that most customers will use to determine whether the raw material is suitable for its proposed application or formulation, and whether the information provided is sufficient to ensure technical suitability and regulatory compliance. Information may include but is not limited to the following:

- Appearance
- Odour
- Peroxide value
- Acid value
- Density
- Refractive index
- Solubility
- Viscosity
- Product applications
- Product clinical trials
- Any information available on the performance of the product

Chemical composition

The main components of the product and their concentration ranges should be listed, as well as minor components that contribute to the hazard classification or could adversely affect a cosmetic product.

If components are unintended, unavoidable, or not a deliberate component of the product, such as heavy metals, pesticides or other contaminants introduced during manufacturing, packing or storage, they must be mentioned in relation to regulatory limits. If solvents or any other chemical are added during extraction and manufacture, their residue range should be provided.

Additional information

The shelf life and expiry date should be listed, as well as the storage method required to avoid degradation, and factors affecting the product's stability.

The main uses of the product should be listed, to allow the customer to assess if the product meets their requirements.

Typical uses of oils

Vegetable oil	Essential oil
Cosmetics	Cosmetics
Personal care products	Personal care products
Food	Perfumes & fragrances Food flavourings

Packaging and handling

Specific handling requirements for the product should be stated, along with any personal protective equipment needed.

Packaging and storage information and instructions should be provided to ensure the quality of the product is maintained throughout its shelf life. Any incompatible materials should be mentioned.

Product Data Sheet (PDS)

A Product Data sheet (PDS) is also known as a Product Information sheet (PIS). It will typically include information about the general identity of the product, basic composition, microbiology results and regulatory information.

Typical information on a Product Data Sheet

	Seed or vegetable oil	Essential oil
General information, identification & product description		
Manufacturer/supplier information	X	X
General identification	X	X
Trade name		
Chemical name		
INCI name		
CAS number		
EC number		
REACH registration number		
Additional information		
Product information		
Country of origin	X	X
Product description	X	X
Origin of starting material	X	X
<i>If the product or substance is of plant origin, the PDS should identify the common names of the plant and its family, genus, species, variety and cultivar; and whether it is cultivated or harvested from the wild</i>	X	X
Description of the natural habitat and geographical distribution of the plant		
Description of the product or substance's commercial form: e.g. powder, liquid, solution, paste, etc.		
Production process – general description	X	X
Function/s related to cosmetics	X	X
Chemical composition, additives, and unavoidable material		
Fatty acid composition – main components	X	
Main components – analysed by a gas chromatographic (GC) profile		X
Preservatives	X	X
Allergens	X	X

	Seed or vegetable oil	Essential oil
Antioxidants	X	X
Residual solvents	X	X
Bleaching agents	X	X
Fragrances	X	X
Heavy metals	X	X
Pesticides	X	X
Contaminants or by-products from the manufacturing process	X	X
Microbiology		
<i>E. coli</i>	X	X
Total coliform count	X	X
Total plate count	X	X
Yeast and mould count	X	X
<i>S. aureus</i>	X	X
<i>P. aeruginosa</i>	X	X
Mycotoxins		
Aflatoxin	X	X
Fumotoxins	X	X
Ochratoxins	X	X
Zearlaleone	X	X
Regulatory		
Animal testing statement	X	X
CMR declaration including avoidable and unavoidable contaminants from manufacturing, inherent from starting material, or leaching from packaging	X	X
Bovine Spongiform Encephalopathy (BSE) declaration	X	X
GMP statement/accreditation	X	X
GMO status	X	X
EU regulatory restrictions or prohibitions	X	X
Other regulatory compliance statements	X	X

General information, identification and product description

This section of a PDS includes the general identification information of the supplier or manufacturer and the product. Typically, the trade name/s, chemical name and INCI name of the product is provided as well as the CAS number, EC number and REACH registration number, where applicable. Additional information on the identity of the product should be provided as far as possible.

Product information

General information on the product is provided, such as the country of origin and a description of the product. This section should also include the origin of the starting material; i.e. plant, animal, mineral or synthetic, etc.

All vegetable oils and essential oils are derived from plant material and the PDS should include the common or usual name of the plant, name of variety or varieties, cultivars, species, genus, and family.

It should specify whether a plant is cultivated or harvested from the wild, and include a description of its natural habitat and geographical distribution; as well as its commercial form (e.g. powder, liquid, solution, paste, etc.)

A general description of the production process should also be included.

If the oil is to be used in cosmetic products, the function/s of the oil should be described.

The PDS should preferably provide any supporting GLP test results or clinical studies to support the oil. This information is required for products that are intended to be used as cosmetic raw materials or cosmetic final products for the Product Information File (PIF) and the cosmetic safety assessment as per the Cosmetic Regulation EC 1223/2009.

Chemical composition, additives, and unavoidable materials

The main components and their concentration ranges should be listed, as well as any minor components that contribute to the hazard classification or could adversely affect the toxicity of a cosmetic product. Note that the contaminant may not contribute to the CLP classification but could have a profound toxicological impact on human exposure.

If solvents or other chemicals were used in the extraction or manufacturing process, their residual range should be provided. The PDS should include any added preservatives or antioxidants, and their chemical identity and concentration range. Unavoidable materials, components or contaminants such as pesticide residue or heavy metals, or contaminants resulting from packaging (e.g. phthalates) or as a result of storage and oxidation (e.g. aldehydes and ketones) should be provided with reference to their regulatory limits. This information is important for products being used as a cosmetic raw material or cosmetic final product, as it is used in the Product Information File (PIF) and the cosmetic safety assessment.

Microbiology and mycotoxins

To ensure safety of the raw materials, all products should undergo microbiology testing as part of the quality control process. There are many stages during production that could lead to possible contamination, such as handling and processing of raw materials, or packaging and storage of final products.

Mycotoxins, which are toxic secondary metabolites produced by different types of fungi, can be present in seeds which are used as raw materials for vegetable oils. If these contaminated seeds are not removed before the processing, these mycotoxins can be transferred to the finished product.

Regulatory

Regulatory statements, declarations or certificates related to the product and its production should be stated; as well as anything related to animal testing, GMP, CMRs (carcinogen, mutagen and reproductive toxins) contaminants. A BSE declaration and other relevant certifications or approvals (e.g. EcoCert) should also be mentioned.

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