



Petition - Overview

US (FDA) & EU (EFSA, ECHA) & DE (BfR, UBA) & CH (BLV)

- I GENERAL INFORMATION
- II CHEMISTRY INFORMATION
 - A. Identity of Substance (FCS)
 - 1. CAS name
 - 2. CAS registry number
 - 3. trade or common name
 - 4. other chemical name
 - 5. Description (structure, molecular weight, distribution)
 - 6. Characterisation (IR, UV, NMR, mass spectra)
 - B. Manufacture
 - 1. reagents used
 - 2. manufacturing process (reaction scheme, conditions, purification)
 - 3. impurities (chemical id., residual levels, analytical methods and validation)
 - C. Physical/Chemical Specification
 - 1. FCS (density, melting point, maximum impurity levels, solubility in food simulants).
 - 2. polymeric FCS
 - a) molecular weight distribution, glass transition, viscosity, MFI, morphology, crystallinity)
 - b) molecular weight profile (max. percentage oligomers below 1000 g/mol)
 - D Intended use
 - 1. Intended use (type of FCM, i.e. plastic, coating, etc., maximum thickness, maximum use level)
 - 2a) single use article (type of foods, contact conditions)
 - 2b) repeated use article (use scenario, highest temperature, maximum contact time, amount of food)
 - 3. intended technical effect
 - E. Stability data
 - 1. degradation, decomposition, other chemical breakdown process, also during migration testing
 - 2. break down products (identity, amount and migration)
 - F. Migration levels in food
 - a) experimental determination
 - b) calculation (100%) or estimation (modelling)
 - c) summary of migration testing
 - d) summary of method validation (stability, recovery and validation by fortification)
 - G. Estimated daily intake
 - 1. single use articles
 - 2. repeated use articles
 - 3. summary of chemistry information
- III TOXICOLOGY INFORMATION - SAFETY NARRATIVE
- IV ENVIRONMENTAL INFORMATION
- V CERTIFICATION
- VI ATTACHMENTS - REFERENCES (Literature, MSDS, TDS, etc.)

additional information

- VII DATA ON AUTHORISATION
- VIII RESIDUAL CONTENT IN FCM
- IX MICROBIOLOGICAL PROPERTIES

safe.PETITION™ integrates all actions to be taken for notification of new Food Contact Substances (FCS) or Drinking Water Contact Substance (DWCS), from the production of test samples down to support at authorities and makes use of advanced scientific techniques like migration modelling to guarantee highest time and costs efficiency and guarantees the highest degree of overlapping for a combined EFSA & FDA notification resulting in significant savings.

safe.PETITION™ is in full agreement with the following guidelines:

- EFSA's (& BfR & UBA) "Note for Guidance"
- FDA's "Guidance for Industry, Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations"
- ECHA's approach (in preparation)

The following modules are to be considered:

- [A] petition.DATA
Gathering of information and definition of petition task.
- [B] pre.TEST
Characterization of food contact substance and food contact material incl. non-intentionally added substances and preliminary migration modeling.
- [C] migration.STUDY
- [D] safe.EXPO
Exposure assessment including dietary concentration calculation.
(mandatory for FDA, may be required for NIAS for EFSA)
- [E] safe.CTP
Comprehensive toxicological profile
(toxicological studies to be provided by customer)
- [F] safe.PETITION
Dossier compilation for safety evaluation of the FCS by the competent authority (EFSA, FDA, BfR, UBA, ECHA, etc.) including safety narrative
- [•] petition.ASSIST
Any other services and support.

The petition dossier preparation including gathering of information, consultation with customer, laboratory and agency, elaboration of a comprehensive toxicological profile (CTP) based on existing toxicological data, estimated daily intake (EDI) based on enhanced exposure scenario, and any other service, are charged based on the daily rate for services.

- For services the following daily rates (in-house) apply: 1.920,- EUR/day (240,- EUR/hour)
- For travelling and accommodation daily travelling flat rates apply 990,- EUR/day (DE, first day)

For unforeseeable intricacies a safety margin of 30% on the whole budget is foreseen which will be charged only based on detailed justification.

Costs will be charged based on real expenses. All costs are exclusively VAT.

The above given figures are for orientation only !

A detailed offer will be issued as soon as all relevant information for the safe.PETITION™ are available.