

Reference Materials for Extractables and Leachables Testing

Certified reference material mixes and neat reference materials for accurate analysis

Extractables and Leachables (E&L) are chemical compounds with the potential to migrate into pharmaceutical or clinical products from packaging materials, tubings or medical devices. This can lead to patient exposure to these compounds. Extensive E&L studies to identify compounds that might leach into the product are obligatory for pharmaceutical products and medical devices.

Since it is never entirely predictable which chemicals could migrate, it is crucial that no potential extractables and leachables are overlooked in the analysis. Depending on the nature of the packaging material, the product and the applied conditions, new unexpected or unknown compounds may be found. There is therefore no finite list of analytes to be tested for. However, there are certain monomers or additives that are more commonly detected in studies examining extractables and leachables.

To facilitate your identification and quantification of these extractables and leachables, we developed two certified calibration mixes to help streamline your analysis. One mix is designed for LC (21 components) and another one for GC detection (14 components). These two products are Certified Reference Materials (CRM) produced under ISO/IEC 17025 and ISO 17034 double accreditation:

- Certification of each individual component by qNMR (following ISO 17025 accreditation)



- Mixes produced following the ISO 17034 workflow
- Tested for homogeneity and long-term stability using GC-MS
- Traceability to NIST SRM
- Supplied with a comprehensive certificate including the overall uncertainty

The components were chosen to reflect a broad spectrum of typical extractables and leachables compound classes taking into account the toxicity and also how frequently they are typically found in E&L tests. The compositions are shown in the following tables.

LC Mix

Product Number	95636
Product Name	Extractables and Leachables Screening Standard for LC
Suffix	Certified Reference Material TraceCERT
Solvent	Acetonitrile
Concentrations	50 µg/mL per component
Package Size	1 mL

Product Name	CAS	Name	CAS
Irganox 1010 (Ir 1010)	6683-19-8	Butylhydroxytoluene (BHT)	128-37-0
Irganox 1076 (Ir1076)	2082-79-3	1,3-Di-tert-butyl-benzene (DBB)	1014-60-4
Dometrizol (Dome) / Tinuvin P/2-(2H-Benzotriazol-2-yl)-p-cresol	2440-22-4	Oleamide (Ole)	301-02-0
ε-Caprolactam (CAP)	105-60-2	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7
Dibenzylamine (DBA)	103-49-1	Stearic acid (SA)	57-11-4
Benzoic acid (BA)	65-85-0	Erucamide (Eruca)	112-84-5
2-Mercaptobenzothiazole (2-MBT)	149-30-4	Irganox 3114 (Ir3114)	27676-62-6
Bisphenol A (BPA)	80-05-7	Irgafos 168-oxide	95906-11-9
2-Ethylhexanoic acid (EHA)	149-57-5	2,4-di-tert-Butylphenol	96-76-4
Bis(4-chlorophenyl)sulfone (CPS)	80-07-9	Palmitic acid	57-10-3
2,6-Di-tert-butyl-4-hydroxymethyl-phenol (DBOHP)	88-26-6		

GC Mix	
Product Number	01829
Product Name	Extractables and Leachables Screening Standard for GC
Suffix	TraceCERT® Certified Reference Material
Solvent	TBME
Concentrations	50 µg/mL per component
Package Size	1 mL

Product Name	CAS	Product Name	CAS
Irganox 1076 (Ir1076)	2082-79-3	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7
ε-Caprolactam (CAP)	105-60-2	Stearic acid (SA)	57-11-4
2-Mercaptobenzothiazole (2-MBT)	149-30-4	Erucamide (Eruca)	112-84-5
Bisphenol A (BPA)	80-05-7	Irgafos 168-oxide	95906-11-9
Butylhydroxytoluene (BHT)	128-37-0	2,4-di-tert-Butylphenol	96-76-4
1,3-Di-tert-butyl-benzene (DBB)	1014-60-4	2,6-di-tert-Butylphenol	128-39-2
Oleamide (Ole)	301-02-0	Palmitic acid	57-10-3

Neat Certified Reference Materials

In addition to the mixes, we also offer a series of certified reference materials and reference materials in neat format. The most recent additions to this range are listed below. These products are provided with a NIST SRM traceable value determined by quantitative NMR (qNMR) in accordance to ISO/IEC 17025 and in the case of the CRMs

also ISO 17034. The values are given with an uncertainty value which takes the stability and homogeneity of the material into account. WE are continuously expanding our range of extractables and leachables reference materials. Please do regularly check our website for the most recent product additions.

Cat.No.	Product Name	Synonym	CAS	Package Size
78274	Benzophenone		119-61-9	100 mg
90048	Bis(2,4-di-tert-butylphenyl) phosphate		69284-93-1	100 mg
CRM96153	Bis(4-chlorophenyl) sulfone	CPS	80-07-9	100 mg
CRM96142	Bis[4-(glycidylloxy)phenyl]methane, mixture of isomers	Bisphenol F diglycidylether (BPFE)	2095-03-6	100 mg
CRM01483	e-Caprolactam	CAP	105-60-2	100 mg
78270	1-Decene		872-05-9	100 mg
CRM95728	Dibenzylamine	DBA	103-49-1	100 mg
78132	Didodecyl 3,3'-thiodipropionate		123-28-4	100 mg
78478	7,9-Di-tert-butyl-1-oxaspiro[4.5]deca-6,9-diene-2,8-dione		82304-66-3	50 mg
CRM96857	3,5-di-tert-butyl-4-hydroxybenzyl alcohol	2,6-Di-tert-butyl-4-hydroxymethyl-phenol (DBOHP)	88-26-6	100 mg
CRM96659	1,3-Di-tert-butylbenzene	DBB	1014-60-4	100 mg
CRM00437	2,4-Di-tert-butylphenol		96-76-4	100 mg
CRM96852	2,6-Di-tert-butylphenol		128-39-2	100 mg
78290	Docosane		629-97-0	100 mg
CRM01374	cis-13-Docosenoamide	Erucamide (Eruca)	112-84-5	100 mg
78292	Eicosane		112-95-8	100 mg
78699	Ethyl 4-ethoxybenzoate		23676-09-7	100 mg
78263	Ethylene glycol butyl ether		111-76-2	100 mg
78293	Hexadecane		544-76-3	100 mg
CRM96697	2-(2-Hydroxy-5-methylphenyl)benzotriazol	Dometrizol (Dome) / Tinuvin P	2440-22-4	100 mg
78345	Isophorone		78-59-1	100 mg
78266	Isovaleric acid		503-74-2	100 mg
CRM96051	2-Mercaptobenzothiazole	2-MBT	149-30-4	100 mg
78289	2-Methyldodecane		1560-97-0	100 mg
78294	Octadecane		593-45-3	100 mg
78295	1-Octadecene		112-88-9	100 mg
CRM00318	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	Irganox 1076 (Ir1076)	2082-79-3	100 mg
78340	1-Octene		111-66-0	100 mg
CRM96709	Oleamide	Ole	301-02-0	100 mg
CRM96656	Pentaerythritol tetrakis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)	Irganox 1010 (Ir 1010)	6683-19-8	100 mg
CRM96839	Tris(2,4-di-tert-butylphenyl)phosphate	Irgafos 168-oxide	95906-11-9	100 mg
CRM96737	Tris(3,5-di-tert-butyl-4-hydroxybenzyl) isocyanurate	Irganox 3114 (Ir3114)	27676-62-6	100 mg

The two mixes and the neat reference materials can be found on our webpage in addition to a list of more than 100 certified reference materials and analytical standards for commonly found extractables and leachables

[SigmaAldrich.com/extractablesandleachables](https://www.sigmaaldrich.com/extractablesandleachables)

