

Reference Materials for Extractables and Leachables Testing

New 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 Reference Materials

In addition to the mixes, we recently added a series of 16 new reference materials to this range which are listed below. These new products are provided with a NIST SRM traceable value determined by quantitative NMR (qNMR) in accordance to ISO 17025. The values are given with an uncertainty value which takes the stability

and homogeneity of the material into account. We are also developing certified reference material (CRM) mixes for LC and GC to cover a broad range of compound classes that are most commonly found in extractables and leachables studies. Please do regularly check our website for the most recent product additions.

Cat.No.	Product Name	Synonym	CAS	Package Size
96656	Pentaerythritol tetrakis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)	Irganox 1010 (Ir 1010)	6683-19-8	100 mg
00318	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	Irganox 1076 (Ir1076)	2082-79-3	100 mg
96697	2-(2-Hydroxy-5-methylphenyl)benzotriazol	Dometrizol (Dome) / Tinuvin P	2440-22-4	100 mg
01483	ε-Caprolactam	CAP	105-60-2	100 mg
95728	Dibenzylamine	DBA	103-49-1	100 mg
96051	2-Mercaptobenzothiazole	2-MBT	149-30-4	100 mg
96142	Bis[4-(glycidyoxy)phenyl]methane, mixture of isomers	Bisphenol F diglycidylether (BPFE)	2095-03-6	100 mg
96153	Bis(4-chlorophenyl) sulfone	CPS	80-07-9	100 mg
96857	3,5-di-tert-butyl-4-hydroxybenzyl alcohol	2,6-Di-tert-butyl-4-hydroxymethylphenol (DBOHP)	88-26-6	100 mg
96659	1,3-Di-tert-butylbenzene	DBB	1014-60-4	100 mg
96709	Oleamide	Ole	301-02-0	100 mg
01374	cis-13-Docosenoamide	Erucamide (Eruca)	112-84-5	100 mg
96737	Tris(3,5-di-tert-butyl-4-hydroxybenzyl) isocyanurate	Irganox 3114 (Ir3114)	27676-62-6	100 mg
96839	Tris(2,4-di-tert-butylphenyl)phosphate	Irgafos 168-oxide	95906-11-9	100 mg
00437	2,4-Di-tert-butylphenol		96-76-4	100 mg
96852	2,6-Di-tert-butylphenol		128-39-2	100 mg

The two mixes and the 16 new 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)

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