



# Corporate General Specification

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## European Union RoHS Specification

<b>Description:</b>	EU RoHS Specification	<b>Latest Update:</b>	03/02/18
<b>Specification No:</b>	110	<b>Supersedes all previous versions</b>	
<b>Owner:</b>	Medical Department Toxicology & Compliance Solutions		

**SCOPE:** This specification establishes the requirements for complying with the substance restrictions of European Union (EU) Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended by Commission Delegated Directive (EU) 2015/863. The EU RoHS Directive and subsequent amendment to Annex II restricts lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and/or diisobutyl phthalate (DIBP) in certain electrical and electronic equipment, except for certain maximum concentration levels in homogeneous materials and except for certain listed exemptions. This specification applies to all materials, parts, components and/or products (whether finished or semi-finished) that include restrictions on the EU RoHS substances (listed in Table 1 below) or a citation to this specification on or in their 3M part number drawing, part or product specifications, sourcing agreements, purchase contracts, purchase orders or other purchasing documentation. This specification does not apply to batteries.<sup>1</sup> In addition to this specification, 3M maintains environmental and/or related requirements in other specifications, contracts, purchase orders, or procurement documents. Full compliance requirements for the RoHS Directive are not solely a part of this specification, but are applied through the combination of this specification, other applicable contract or purchase order provisions, and other applicable 3M product specifications.

### 1.0 DEFINITIONS:

“Homogeneous material” means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.<sup>2</sup> Examples of homogeneous materials include a plastic cover to a computer screen, a copper wire inside a cable, and the solder part of a solder joint.<sup>3</sup> All EEE consist of many different homogeneous materials and the maximum concentration values are applied to each of the homogeneous materials individually.

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<sup>1</sup> The EU RoHS Directive does not apply to batteries, which are subject to other Directives and regulations globally. Accordingly, this RoHS Specification does not apply to batteries. Material content limits on batteries in materials, parts, components and/or products may be specified separately.

<sup>2</sup> The definition of “homogeneous materials” (in this first sentence) is taken from the recast RoHS Directive 2011/65/EU, Article 3(20).

<sup>3</sup> The examples included in this definition are contained in the Frequently Asked Questions (FAQs) on the RoHS Directive 2011/65/EU, EC Directorate-General Environment (12 December 2012). Note that this document has been labeled “not legally binding” and therefore these examples are subject to change.

“EU RoHS” refers to the European Union’s Directive 2011/65/EU.

“Commission Delegated Directive (EU) 2015/863” or “Directive 2015/863” establishes four additional substances (four phthalates) to be restricted in EEE through its amendment to Annex II of EU RoHS (2011/65/EU).

## 2.0 REQUIREMENTS:

Except as provided for below in Section 3, “Exemptions,” any materials, parts, products and components covered by this specification may not contain more than the Table 1 maximum concentration levels of EU RoHS restricted substances in any “homogeneous materials.”<sup>4</sup> It is possible that 3M business units may set lower thresholds.<sup>5</sup> In case of conflicts with product specifications or other written 3M requirements, the more restrictive specification or requirement shall be followed.

**Table 1. Maximum Concentration Values**

<i>Substance (or compound containing this substance)</i>	<i>Maximum Concentration Level</i>
Lead (Pb)	0.1% by weight in homogeneous materials
Mercury (Hg)	0.1% by weight in homogeneous materials
Hexavalent Chromium (Cr+6)	0.1% by weight in homogeneous materials
Cadmium (Cd)	0.01% by weight in homogeneous materials
Polybrominated Biphenyl (PBB) flame retardants	0.1% by weight in homogeneous materials
Polybrominated diphenyl ether (PBDE) flame retardants	0.1% by weight in homogeneous materials
Bis(2-ethylhexyl) phthalate (DEHP)	0.1% by weight in homogeneous materials
Butyl benzyl phthalate (BBP)	0.1% by weight in homogeneous materials
Dibutyl phthalate (DBP)	0.1% by weight in homogeneous materials
Diisobutyl phthalate (DIBP)	0.1% by weight in homogeneous materials

These levels apply to the substance as well as any compounds containing the substance.

## 3.0 EXEMPTIONS:

Certain applications are exempt from the EU RoHS Directive, as listed in and if not expired under the term provided in the RoHS Directive 2011/65/EU, as amended, or in Annex III or Annex IV. Those applications (if their term is not expired) are exempt from Section 2 Requirements of this specification.<sup>6</sup>

## 4.0 VERIFICATION OF COMPLIANCE:

4.1 At 3M's request, suppliers will complete 3M supplier questionnaires or 3rd party questionnaires sent on behalf of 3M that certify/verify that the supplied products comply with the substance restrictions of EU RoHS. In addition, at 3M's request, the supplier will verify that products comply with the EU RoHS substance restrictions at supplier’s expense via analytical testing by an independent third party laboratory as per Section 4.2 below. Supplier must conduct appropriate EU RoHS substance restriction conformity and risk assessments on their suppliers and supplied

<sup>4</sup> These maximum concentration values are specified in the EU RoHS Directive 2011/65/EU, Annex II as amended by Directive 2015/863.

<sup>5</sup> Different restricted substance maximums may exist for these 10 chemical categories due to other laws and regulations or customer requirements, for electrical and electronic equipment and other products, and may be specified separately by 3M businesses.

<sup>6</sup> For example, exempt applications include but are not limited to mercury in certain lamps, and lead or cadmium in certain applications. See the EU RoHS Directive 2011/65/EU, Annex III and Annex IV for a complete listing and for the expiration dates of exempt applications.

materials, apply appropriate product design control and manufacture control, and maintain records on compliance of the supplied products with the substance restrictions of EU RoHS, including all analytical test data regarding EU RoHS substances and any test data or EU RoHS certifications provided to suppliers by their suppliers. At 3M’s request, suppliers must make these records available to 3M. At the reasonable request of suppliers, 3M is willing to enter into confidentiality agreements regarding these records.

- 4.2 Any analytical testing should be performed on “homogeneous materials.” In addition, certified analyses should be conducted (including for purposes of sample preparation and test standards). A certified analysis is defined as the use of a referenced EPA (or equivalent)<sup>7</sup> test method that is performed at an ISO17025 accredited laboratory (or equivalent<sup>8</sup>). Representative certified test methods include but are not limited to the listing in Table 2.

**Table 2. Certified Analytical Test Methods<sup>a</sup>**

Substance	Test Method	Method Summary
Cadmium, Lead, Mercury	<i>Preparation</i> EPA 3052	Total decomposition with various acids (microwave)
	<i>Analysis</i> EPA 6010B EPA 7471A	ICP-AES for Cd and Pb CVAAS for Hg
Chromium (VI)	<i>Preparation</i> EPA 3060A	Alkaline digestion
	<i>Analysis</i> EPA 7196A	IC or Diphenylcarbazide adsorption
Polybrominated biphenyl (PBB), Polybrominated diphenyl ether (PBDE)	<i>Preparation</i> EPA 3540C	Soxhlet extraction
	<i>Analysis</i> EPA 8082 (modified)	GC/MS and/or LC/MS
Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP)	CPSC-CH-C1001-9.3, EN14372	GC/MS

<sup>a</sup> Recommended test method or equivalent. Certified analysis includes two matrix spike samples and two duplicate samples for each test matrix.

## 5.0 VARIANCE:

Suppliers seeking a variance or temporary waiver of restrictions in the 3M EU RoHS Specification must make a request to 3M and receive 3M’s written approval. Contact 3M at 1-800-3M-HELPS or send us a message at [3M Help Center](#) for more information on this process.

<sup>7</sup> Equivalent test methods in the EU can be determined as follows, based on equivalency of quality control methods. An analytical method is considered “equivalent” to a referenced EPA method if the method is technically equivalent and includes at a minimum the quality control elements of duplicate sample analyses and duplicate matrix spike analyses for every test matrix (e.g., for every homogeneous sample matrix). EN 13346:2000 applied with the additional quality control elements of duplicate sample analyses and duplicate matrix spike analyses for every homogeneous sample matrix is considered “equivalent” to EPA 3052.

<sup>8</sup> ILAC full signatory members are accreditation bodies that are equivalent to ISO/IEC 17025:2005 accreditation bodies. According to the ILAC Mutual Recognition Arrangement each full member (signatories) agrees to maintain conformance with ISO/IEC 17011:2004 (guidance for accrediting bodies) and ensure that all accredited laboratories comply with ISO/IEC 17025:2005 (laboratory accreditation standard). Therefore, any labs accredited by ILAC accreditation bodies are recognized as ISO/IEC 17025:2005 compliant. <http://www.ilac.org/>

**6.0            REFERENCES:**

RoHS Directive 2011/65/EU:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065>

Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU regarding the list of restricted substances:

[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2015.137.01.0010.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.137.01.0010.01.ENG)

Frequently Asked Questions (FAQs) on the RoHS Directive 2011/65/EU, EC Directorate-General Environment (12 December 2012):

[http://ec.europa.eu/environment/waste/rohs\\_eee/pdf/faq.pdf](http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf)

United States Environmental Protection Agency, “Test Methods for Evaluating Solid Waste,” SW-846, 3rd Edition:

<https://www.epa.gov/hw-sw846/sw-846-compendium>

**\*\* End of Document \*\***