

NeuroLogica Corporation on RoHS European Directive Compliance

The restriction of the use of certain hazardous substances, also known as RoHS, was adopted by the European Union and took effect on July 1, 2006. This RoHS 2002/95/EC directive restricts the use of six hazardous substances in the manufacture of electronic and electrical equipment. On July 21, 2011, a recast of the original Directive became law and took effect January 2, 2013. The 2011/65/EU Directive addresses the same substances as the original directive while improving regulatory conditions and legal clarity. All medical devices, which were previously exempt from the original directive, are now included in the recast to comply with the regulations by July 22, 2014.

In anticipation of international laws and regulations related to the RoHS directive, NeuroLogica has initiated a project to investigate, evaluate, and qualify the materials used in production and in the final product. The hazardous substances and their limits are as follows:

Substance	Maximum Concentration Values Tolerated by Weight	Maximum Concentration Values Tolerated by Parts per Million
Lead	0.1%	1000
Mercury	0.1%	1000
Hexavalent Chromium	0.1%	1000
Polybrominated Biphenyls (PBB)	0.1%	1000
Polybrominated Diphenyl Ethers (PBDE)	0.1%	1000
Cadmium	0.01%	100

However, some products may contain hazardous substances above the limits, as deemed permissible under the RoHS exemptions. NeuroLogica identifies several of the exemptions from the Annex III of the 2011/65/EU directive that are used in the product:

Exemption	Description
6 (a)	Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0.35 % lead by weight
6 (b)	Lead as an alloying element in aluminum containing up to 0.4 % lead by weight
6 (c)	Copper alloy containing up to 4 % lead by weight
7 (a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)
7 (c) – I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectric devices, or in a glass or ceramic matrix compound
7 (c) – II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher
8 (b)	Cadmium and its compounds in electrical contacts

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Along with the exemptions listed herein, the RoHS directive specifies additional exemptions specific to medical devices and monitoring and control instruments. As a medical device company that manufactures computed tomography, NeuroLogica identifies with all the applications exempt from the restriction listed in Annex IV of the 2011/65/EU directive. Currently there are no expiration dates for the exemptions called out from Annex III and the entire Annex IV.

Being a leader in the industry for portable computed tomography technology, NeuroLogica is committed to being compliant with the latest RoHS directive. As technology advances and new materials are released in the market, NeuroLogica is dedicated to moving toward a fully compliant product line. However, as of this date, NeuroLogica cannot be fully compliant. The products will contain some of the banded substances, but within the exempted limits. NeuroLogica takes great consideration of components used, but as section 18 of the 2011/65/EU directive states:

Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured.

NeuroLogica will exercise the use of exemptions listed in the latest directive.

NeuroLogica bases its knowledge of the substance content of its products on information provided by third parties such as suppliers and test laboratories. NeuroLogica will continue to monitor the RoHS regulations for any new directives and regulations.



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