

Visottica Industrie Spa Informative Report according to the provisions of California State Law “Prop. 65”

Dear Customer,

“**The Safe Drinking Water and Toxic Enforcement Act of 1986**”, better known as “**Proposition 65**” or “**PROP.65**”, is a California State law that requires businesses to notify consumers in California when products they seek to purchase contain substances that have been determined to cause cancer, birth defects or other reproductive harm. Visottica Industrie Spa is fully aware of this law, and closely observes its development (the updated list of chemicals known to the State of California to cause cancer or reproductive toxicity is downloadable at <http://oehha.ca.gov/prop65.html>).

Metal components:

In consideration of this preamble, Visottica Industrie Spa informs that in some of its metal components there could be chemicals known to the State of California to cause cancer, birth defects or other reproductive harm; in particular:

- Nickel (CAS No. 7440-02-0), which can be present (6÷65% w/w) in the metal alloys constituting the articles produced and/or commercialized by Visottica Industrie Spa. However Visottica Industrie Spa believes that using these items properly, and thus not putting them in direct and prolonged contact with the skin or covering them with appropriate Nickel-free coatings, the risks related to the use of this chemical could be reduced.
- Lead (CAS No. 7439-92-1), which is present (0.5÷3.5% w/w) in the following articles of 2017 Visottica Comotec catalogues:

Nuts	01DA2601000	01DA26010001	01DA26020000	01DA26020001
	01DA2002200	01DA20022001	01DA22020000	01DA22020001
	01DA2001000	01DA20010000	01DA22011000	

At the same time, Visottica Industrie Spa wants to clarify that also some articles that are not present in 2017 Visottica Comotec catalogues may contain Lead with standards higher than the restrictions fixed by Proposition 65. Upon customer's request, Visottica Industrie Spa is fully available to supply information about the possible Lead presence in these articles.

Plastic components:

For what concerns plastic components produced and/or commercialized, Visottica Industrie Spa informs that the following chemicals known to the State of California to cause cancer, birth defects or other reproductive harm may be present in some of its articles:

- Bisphenol A (CAS No. 80-05-7), or BpA, that can be present in trace levels in the polymer matrix of Polycarbonate material, since BpA is the monomeric building block used during chemical process of polymerization. About BpA, its effects and its possible presence in Visottica Comotec articles please see the attached Visottica Industrie Spa PROP. 65/Bisphenol A Informative Note.

With this notice Visottica Industrie Spa considers as fulfilled the dispositions of law; to this end, it is actually important to remember that PROP. 65 doesn't forbid the use of the listed substances, but only impose companies to provide a "clear and reasonable" warning in case those products expose California consumers to one or more of these chemicals. According to Proposition 65, providing this kind of information makes Californians conscious and able to take responsible decisions about the way of protecting themselves from exposure to these chemicals.

Considering the dynamic nature of the list published by California State, Visottica Industrie Spa will keep on monitoring it periodically and will update this Informative Report in case of requirement to use further listed chemicals for its metal or plastic products.

An updated copy of this Informative Report is downloadable from the website visotticacomotec.com.

Best regards,

Visottica Industrie Spa
Chief Operations Officer
Mr. Daniele Angeli

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Attached: Visottica Industrie Spa PROP.65/Bisphenol A Informative Note.

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Visottica Industrie Spa Proposition 65/Bisphenol A Informative Note

Background: Bisphenol A (BpA) in California Proposition 65

In May 2015 the State of California added Bisphenol A (the monomer BpA, not the derived polymers) to the Proposition 65 list of substances known to the State of California to cause cancer, birth defects or other reproductive harm.

Companies manufacturing, distributing, or selling products in California that contain BpA are required to provide a "clear and reasonable warning" or will run the risk of being the basis for a Prop. 65 lawsuit.

During 2016, California Office of Environmental Health Hazard Assessment (OEHHA) has published a "safe harbor level" for BpA under which clear and reasonable warnings are not needed: this limit establishes a MADL of 3µg/day for BpA "from dermal exposure from solid materials".

What is Bisphenol A / Residual content and possible migration of BpA

Bisphenol A (CAS n° 80-05-7) is an organic synthetic compound which is mainly employed to make certain plastics and epoxy resins. Among these, BpA is used as a monomeric building block for the manufacture of Polycarbonate resin. During the chemical process of polymerisation, BpA reacts and becomes firmly bound into the structure, thus actually building the polymer material.

Unavoidable technically trace levels (typically less than 100 ppm, parts per million) may remain in the polymer matrix of all Polycarbonate resins (so-called free or residual BpA) and, therefore, trace levels of BpA can be present also in all Polycarbonate articles.

BpA and articles manufactured from BpA, such as Polycarbonate, have been extensively tested for potential health effects during the years by worldwide research institutes, academic laboratories, governmental institutes and industry. All these tests asserted that there is a low-risk level of migration of BpA from Polycarbonate articles, this risk being below the safety levels set by the government agencies.

Bisphenol A in Visottica Comotec products:

Visottica Industrie Spa has made several external laboratory tests and the results have remarked that, under normal conditions of use, Polycarbonate components produced and/or commercialized perfectly comply with BpA limits fixed by California Proposition 65.

In addition to that, Visottica Industrie Spa wants to underline that Polycarbonate inserts are not in direct and prolonged contact with the skin, since they are embedded into PVC or Silicone nose-pads. This further reduces the risk of migration of Bisphenol A from the Polycarbonate to the skin of the user.

Referring to this last statement, Visottica Industrie Spa wants to clarify that PVC and Silicone raw materials used for the production of its nose-pads do not contain BpA, since this Chemical is not present in their formulation.

With this communication, Visottica Industrie Spa thinks to have clarified all the inquiries on this matter; in any case, Visottica Industrie Spa is fully available to give further information to its customers about Bisphenol A and its possible presence in its articles.

An updated copy of this Informative Note is downloadable from the website visotticacomotec.com.

Best regards,

VISOTTICA INDUSTRIE Spa
Chief Operations Officer
Mr. Daniele Angeli

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