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European Chemicals Agency
ECHA

Schaan, September 2013

Comment regarding the use of aluminium silicate fibres for thermal insulation purposes in the dental ceramic and press furnaces of Ivoclar Vivadent AG

Ladies and Gentlemen

Ivoclar Vivadent AG is a leading international manufacturer of ceramic and press furnaces for the dental industry. These furnaces are used in the fabrication of metal-ceramic and all-ceramic dental restorations. For this purpose, these furnaces need to be heated to temperatures of up to 1200°C.

Vacuum-formed parts made of AlSi - RCF fibres are used as thermal insulation components in these furnaces.

Technical requirements of thermal insulation

The AlSi - RCF materials used in these furnaces meet specific technical requirements, which are listed in detail in the following table. Alternative thermal insulation materials, e.g. refractory bricks and alkaline earth silicate wool (AES), do not meet the technical requirements of firing chambers in particular. Wherever technically feasible, suitable thermal insulation products are used.

Requirements	Technical shortcomings of alternative materials for the thermal insulation of dental furnace chambers
Resistant to changing temperatures with heating gradients ranging from tmax to 140K/min from Rt to 1200 °C and very steep cooling gradients within 5s due to opening of the firing chamber, also at a firing	Vacuum-formed parts based on AlSi - RCF fibres can be produced with a soft core and a hardened surface. These components fulfil the thermal endurance requirements of firing chambers. Under these extreme conditions, some alternative products already start to crack and break when the furnace is heated up for the first time.

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Requirements	Technical shortcomings of alternative materials for the thermal insulation of dental furnace chambers
chamber temperature of 1200 °C.	Note: The dimensions of the firing chamber should be quite small in order to take the required temperature gradients into account. The dynamic heating processes for their part produce very steep and high temperature gradients within the insulation.
Maximum operation temperature Tmax = 1200 °C and safety during continuous duty	Due to safety reasons, the fire-proof products must be able to fully withstand the continuous operation of cyclical furnace processes and chemical attacks up to a temperature of 1300 °C. In the event of failure, the protection element in this type of firing chamber is a filament, which has a melting temperature of >= 1260 °C.
Chemical resistance, electrical safety	By-products and fumes, which arise during the firing of dental ceramics, settle in the insulation components and attack and damage the fire-proof material. This lowers the actual max. operating temperature and the safety of the firing process. Furthermore, customers will not tolerate or they will complain if the insulating material stains or loses its shape due to the above influences. In addition, these chemical deposits and contaminants in the fire-proof products and AES thermal insulation materials will lead to undesirable electrical conductivity at the surface of the insulation materials, particularly at rising temperatures. As a consequence, the risk of critically high leakage currents or short circuits between the heating element, which is embedded in the insulation, and the thermocouple, which extends into the firing chamber, will occur. Therefore, the safe operation of our devices would no longer be ensured for our clients.
Heat retention / fast processes	In order to attain high process cycle rates, the heat retention (density) of the insulation materials used must be very low. Nevertheless, the material must be capable of insulating very well. This requirement can only be fulfilled with products made of high-temperature insulation wool (e.g. AlSi - RCF).
Frequency and place of use by	Our clients, that is, dental technicians, work in small

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Requirements	Technical shortcomings of alternative materials for the thermal insulation of dental furnace chambers
our customers (dental lab technicians)	businesses, usually composed of 1 to 3 people. They rarely work in commercial laboratories. Press and ceramic furnaces, apart from other necessary tools, represent very costly investments, which are used on a daily basis. The failure of a furnace leads to a loss of income. Therefore, our clients are highly dependent on the continuous availability of these devices. They count on the reliability of their press and ceramic furnaces to produce high-quality dental products. At an international level, the laboratories which use our furnaces are often very small. As a result, our customers want devices that require very little space and do not produce a lot of heat. Therefore, we are obliged to come up with compact designs and suitable heat insulation solutions. Our customers work in close proximity to their furnaces. Furthermore, our customers look for energy-saving features when they buy a furnace.
Consistent quality	The properties of refractory bricks in particular vary quite considerably, depending on the production batch. As a result, the consistency of the quality and durability of the furnaces may be negatively affected. Moreover, changes in the thermal insulation may also lead to alterations in the temperature regimes in the firing chamber. These changes may have a detrimental but undetected effect on the end product.
Exposure to fibre dust	When the furnaces are fitted with the pre-fabricated AlSi RCF products, the corresponding extraction equipment is used to reduce the exposure to fibres. The factory workers are protected. Furthermore, these people are trained to handle thermal insulation products correctly. When our customers user their furnaces, dust and fibre dust would impair the quality of their dental products. When the dental furnaces are operated, no dust exposure has been established; that is, on or below the detection limit.

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Measures taken by Ivoclar Vivadent in the assembly and servicing of press and ceramic furnaces

The dental press and ceramic furnaces are assembled by Ivoclar Vivadent GmbH in Austria. The service centre, in which the devices are serviced and repaired, is located in the same facility. The following measures are taken to ensure the safe handling of AlSi - RCF fibres at the manufacturing facility in Bürs. The guidelines are provided in safety data sheets.

1) The AlSi - RCF products are supplied in the form of vacuum-formed parts, which are directly installed or mounted without any further mechanical processing. Mechanical work and adjustments are only carried out by the supplier, not by Ivoclar Vivadent GmbH!
2) The employees are trained to handle AlSi - RCF products and follow the guidelines of the safety data sheets. Training measures are conducted on a regular basis and training certificates are issued.
3) Ivoclar Vivadent GmbH actively collaborates with the accident insurance Allgemeine Unfallversicherungsanstalt (AUVA). The insurance company has inspected the manufacturing facility and the working conditions.
4) In 2011, the adherence to threshold values at the manufacturing facility of Ivoclar Vivadent GmbH was inspected by the Austrian Dust-Silicosis Control Centre (ÖSBS). The compliance with threshold value regulations was confirmed. The recommended health-based threshold value of 0.3 f/ml recommended by the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic Fibres (SCOEL) is not reached.
5) The thermal insulation materials are stored in their transport packaging.
6) The areas in which thermal insulation is pre-assembled or disassembled are separated from the other assembly areas.
7) Regularly serviced extraction equipment, together with suitable dust filters, is used at the facility.
8) Waste is separated according to the safety data sheets and collected in the corresponding containers and disposed of accordingly.

Information for the end user

Safety information regarding the handling of the AlSi - RCF products contained in the furnaces is provided for our customers in the Operating Instructions.

Market situation

The international competitors of Ivoclar Vivadent AG likewise use AlSi - RCF products as thermal insulation in their ceramic and press furnaces. Our competitors have also found that the use of alternative products is associated with unjustifiable efforts, costs and compromises with regard to technical properties and performance. Furthermore, a short service life represents a certain occupational safety hazard for the end customer.

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The fabrication, procurement and processing of alternative thermal insulation materials is considerably more expensive than that of the products already in use. At the same time, their service life is shorter, which negatively influences occupational health and safety aspects. Furthermore, our customers would be faced with the additional cost of having to replace the insulation components during the technical lifetime of their press and ceramic furnaces.

Changes in the thermal insulation and slow failure of the furnace can lead to process changes which remain undetected, but cause invisible damage to the end product. Dental restorations made by dental lab technicians are the end products that come out of our press and ceramic furnaces. These restorations are ultimately placed in a patient's mouth by a dentist.

Ivoclar Vivadent AG consistently monitors the developments of manufacturers who supply thermal insulation materials that are not classified as AlSi - RCF fibres. To date, however, no alternative material, which entirely meets our technical and economical requirements, has been identified.

The occupational health and safety measures that apply to the handling of thermal insulation materials and the reduction of possible risks (occupational health and safety) remain the same, irrespective of the fire-proof product used, in order to protect the health of employees and end users.

The health and safety of internal and external staff and customers is of major importance to Ivoclar Vivadent. For this purpose, the company adheres to the described measures and the existing regulations. Currently a European wide binding occupational exposure limit value (BOELV) specifically for alumino silicate RCF is in discussion on European Commission-Level (DG-Employment). Nevertheless, the company is required to maintain a competitive edge at an international level to ensure its continued existence (Art 55 REACH Regulation).

Sincerely

Ivoclar Vivadent AG

P Oehri
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