A Qualitative Overview of the Use of Beryllium, Beryllium-Containing Alloys and Beryllium oxide Ceramic in Electrical and Electronic Equipment (EEE)

Respectfully submitted to the Öko-Institut e.V. to assist its

Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive

for the European Commission

Beryllium industry document prepared by:
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EXECUTIVE SUMMARY

Under Article 6 of Directive 2002/95/EC of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), the European Commission (EC) has initiated a study to evaluate the need to revise the list of substances covered by the RoHS directive. The Öko-Institut e.V. has been contracted by the EC to conduct this study which is described in the project description dated October 17, 2007. The Öko-Institut e.V. expects to complete their evaluation and issue their final report to the EC in June 2008. The EC, following analysis of the final report, must then prepare and submit, if appropriate, proposals for revision of the relevant provisions of the RoHS Directive to the European Parliament and Council for review and adoption.

In its December 2007 study document on the RoHS Directive[1], the EC indicated its intentions to minimize adverse impacts from revisions to European Union (EU) legislation, which includes the RoHS Directive, by stating:

> *"Simplification of legislation has been recognised by the Commission as being a necessity for obtaining legislation which is strong and more effective in achieving its goals. Through simplification, legislation will be more transparent, more focused, more cost effective and more accepted by the target groups. Therefore, in every simplification exercise the first question will always be to save and to promote the goals of the original instrument, but it will do this by using the most suitable, the least burdensome and most effective instruments. The economic principle, to achieve the best results with the least effort, is the guiding principle. A good simplification exercise should be neutral against the goals of the policy; it is merely an instrumental exercise. However, the argument of simplification will often be used to achieve shifts in the level of ambition or in the goals of the legislation, and this is a pitfall to be avoided, particularly in discussions with stakeholders. As described in the request for services, this simplification exercise will scrutinise the current legislative approach with a view to replacing or amending it with more efficient, less prescriptive, flexible and proportionate instruments while maintaining the same level of environmental protection. The proposals formulated in this study seek to maintain the environmental objectives at the least cost possible, including static costs such as administrative burden and dynamic costs such as any effects on innovation."*

In the opinion of many, including Eurometeaux, WVM and IPC, the evaluation and possible addition of other metals to the ROHS Directive is not warranted or necessary and that any restrictions of substances in products would more appropriately be addressed under the current REACH Directive. This is particularly true with regard to the use of beryllium-containing materials. Beryllium metal and composites, beryllium-containing alloys and beryllium oxide (BeO) ceramics are used in critical applications which are vital to European technology, offering property combinations not available in other materials, and allowing European designers to achieve world class levels of innovation, performance, energy efficiency and reliability. Beryllium-containing materials have historically been on the cutting edge in technology development. Today, beryllium-containing materials are being viewed as a technology enabling material in the development of alternative energy sources, particularly in solar technologies and in fusion reactors such as the International ITER Project. The supply and usage of these materials in EEE does not necessitate regulatory controls beyond those already in place.

As beryllium, beryllium-containing alloys and beryllium oxide ceramic are used in electrical and electronic equipment (EEE) and are identified as hazardous substances meeting the criteria for classification as dangerous in accordance with Directive 67/548/EEC, it is expected that these materials will be considered in the Öko-Institut e.V. study. This document provides information about beryllium metal, beryllium-containing alloys and beryllium oxide ceramics as it relates to use of these materials in EEE and the potential health and environmental risks.

The generic EU health classification for 'Beryllium and compounds' is reviewed in this document in terms of beryllium metal and composites, beryllium-containing alloys and beryllium oxide ceramic. As there are no beryllium mining and extraction operations in the EU, beryllium metal and composites, beryllium-containing alloys and beryllium oxide ceramics are imported, supplied and used predominantly in massive form. These materials can be safely processed and recycled. Potential health risks associated with some component manufacturing and recycling operations, which generate airborne respirable particulate in the workplace, are controlled under existing workplace regulations. These potential risks do not exist during the use of EEE containing these materials. Workplace legislation has established occupational exposure limits (OELs) for exposure to airborne beryllium particulate throughout most of the EU.

Additionally, this study must consider the importance of beryllium to the EU. Parliamentary State Secretary Michael Müller emphasized the importance of strategic materials such as beryllium in a speech given at the European Conference on "Integrating Environment, Development and Conflict Prevention" in Berlin, Germany on 29 March 2007. Secretary Müller stated,

> *"Other raw materials deserve our attention just as much as energy resources. "If there is ever a third world war, it will be over energy and raw materials", said former US Defense and Energy Secretary, James Schlesinger. Resource wars will be a key issue in the future, asserted Henry Kissinger. And the Pentagon concluded: "The world is just as vulnerable when it comes to titanium, niobium, tin, beryllium, germanium or platinum as it is with regard to oil". Reserves of other substances such as antimony or indium are likewise limited."*

It is clear that the inclusion of other materials, such as beryllium, in the ROHS Directive will have an adverse impact on the global supply chain. Inclusion of other substances will make this directive less simple, less focused, more costly and not acceptable to the target groups. Inclusion of additional substances will increase the administrative burden and adversely impact innovation. Furthermore, according to the European Topic Centre on Resource and Waste Management from the European Environmental Agency, iron and steel are the most common materials found in electrical and electronic equipment and account for almost half of the total weight of WEEE. Plastics are the second largest component by weight representing approximately 21% of Waste Electrical and Electronic Equipment (WEEE). Non-ferrous metals, including precious metals, represent approximately 13% of the total weight of WEEE and glass around 5%. The Study of the ROHS Directive stated, *"It should be noted that the content (mostly available in weight %) of Cr(VI) in the products analysed, was already little before RoHS (< 0.1 % by weight), and therefore the RoHS directive has no effect."* Considering the fact that nonferrous and precious metals in total only comprise 13% of the electronic waste stream and the minute quantities of beryllium in electronic products (estimated at < 0.0002% in WEEE), it can be reasonably expected that there would be no measurable benefit derived from adding beryllium to the RoHS directive.

This document is intended to provide a brief overview of beryllium, beryllium-containing alloys and beryllium oxide ceramic usage in EEE in the EU as it relates to risks and the environment. Additional information and references that may be required for a detailed analysis can be supplied upon request.

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1. GENERAL INFORMATION

1.2 NATURAL AND ANTHROPOGENIC BERYLLIUM IN THE ENVIRONMENT

First discovered in 1798, beryllium is a naturally occurring element that is present in the earth's crust[2]. Beryllium is typically reported as the 44th most abundant element in the earth's crust. Because it is ubiquitous, beryllium is found in coal, wood, foodstuffs, and gemstones, such as aquamarine and emerald. The general population is exposed to naturally occurring beryllium from ambient air, drinking water, and diet on a daily basis[3]. Average ambient concentrations of beryllium in soil range from 2.8 to 5 mg/kg (ppm). The average ambient concentration in air in the United States is 0.00003 µg/m^3, while the median concentration in cities is 0.0002 µg/m^3.

Beryllium is naturally occurring in ground water and surface water. Beryllium has been measured in ground water at an average concentration of 13.6 µg/l[4] and in surface water at an average concentration of 23.8 µg/l. Concentrations of beryllium in drinking water range from 0.010 to 1.22 µg/l with an average of 0.19 µg/l. An Australian survey found 0.08 µg/l beryllium in rainwater[5].

The U.S. Agency for Toxic Substances and Disease Registry (ATSDR)[3] has estimated that within the United States, about 45% of airborne beryllium is due to anthropogenic releases of beryllium. Natural sources, such as windblown dust and volcanic activity, account for 55% of beryllium released to the atmosphere. Electric utilities comprise about 80% of the anthropogenic emissions, while industry and metal mining accounts for about 20% of the anthropogenic emissions. Beryllium has been measured (fresh weight) in rice at 72 µg/kg, lettuce at 16 µg/kg, kidney beans at 2200 µg/kg, peas at 109 µg/kg, and potatoes at 0.59 µg/kg. Beryllium has been found in cigarettes at up to 0.74 µg per cigarette. The daily intake of beryllium by non-occupationally exposed persons from food and water is approximately 0.52 µg per day with negligible exposures from ambient air. The average burden of beryllium in non-occupationally exposed persons is 200 µg/kg in the lung, whereas beryllium concentrations in other organs are typically below 80 µg/kg.

1.2. BERYLLIUM METAL AND COMPOSITES

Beryllium is a silver-grey metal, the fourth element of the Periodic Table. The substance beryllium is registered under:

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CAS No.:	7440-41-7

The principal properties of beryllium are its low density, high rigidity, structural stability at high temperatures, and heat dissipation. Beryllium is unique among metals in terms of specific rigidity; i.e. the ratio of rigidity to density. The rigidity of beryllium is about 50% greater than that of steel, while its density (1.84 g/cm^3) is about 30% less than that of aluminium. The specific rigidity of beryllium is around six times greater than that of any other metal or alloy. This is an extremely useful property for many aerospace applications, where lightweight structures are required which are resistant to deformation under high stresses or high temperature. It is also a highly desirable property for other applications that are subject to rapid acceleration and deceleration, such as navigational gyroscopes, high speed rotating mirrors and machine spindles. Beryllium remains stable at high temperatures (melting point 1284ºC) and can be used as a heat sink. The Mercury space capsule used beryllium as the heat shield to protect the astronaut during re-entry through the earth’s atmosphere. The use of beryllium played a crucial role in ending World War II and its use in European fighter aircraft allows military pilots to “own the night“ during combat.

Another special property of the metal is that it is highly transparent to X-rays. In foil form, beryllium is used as the window material for X-ray sources and detectors. It is the premier material used to control the high temperature plasma in experimental fusion energy reactors. It is especially useful in security devices and high-resolution medical imaging technology, such as mammography to detect breast cancer.

Beryllium is a very efficient moderator of neutrons, slowing them and reflecting them, a property that finds application in materials test reactors and in fundamental particle physics research, including efforts to develop alternative energy sources. It is an extremely useful alloying element, conferring high strength on several high conductivity alloys, particularly copper-based alloys.

In solid form, as it is normally supplied and used, the metal is stable and inert. It is not radioactive; it is not water-soluble; it is corrosion resistant in normal ambient conditions; it is resistant to high temperatures; and, it does not give off emissions under the normal range of environmental conditions. It may be handled and stored without special precautions.

1.3 BERYLLIUM-CONTAINING ALLOYS

Beryllium is used to provide favourable properties in a number of metallic alloys, principally copper-based alloys. These alloys find a wide variety of applications and it is therefore important to assess the use of these materials in EEE for risks which might be associated with their beryllium content.

In this context, it is important first of all to understand the nature of alloys, and to be aware of discussions surrounding the methods used for their classification for health and environmental hazards. Currently, materials are divided into two categories for classification purposes, i.e. substances (chemical elements and their compounds) and preparations (mixtures of substances), and alloys fall into the latter category. However, whereas a preparation might be a simple mixture of ingredients, without chemical interaction between those ingredients, this is generally not the case for alloys. Alloys are normally prepared by melting the ingredients together. This causes the constituents of the alloy to dissolve into each other, and/or chemically react with each other, to form new ‘phases’ which persist in the alloy when it cools to room temperature. These phases can be simple solid solutions, in which one constituent is dissolved in the other to form a phase which has a unique and crystallographically identifiable microstructure Alternatively, it can result in a composite structure comprising a matrix which itself is a phase with a unique and crystallographically identifiable microstructure, inside of which are found discrete particles or clusters of atoms of another phase with a unique and crystallographically identifiable microstructure frequently referred to as precipitates which are dispersed on specific and characterising locations within the crystalline structure of the matrix. In either case, it is generally not possible to simply re-separate the constituents from the alloy, as it might be from a simple mixture, without resorting to extraction metallurgical techniques.

This has important implications for the health and environmental classification of alloys. It is a fact that the chemical, physical and mechanical properties of an alloy can be quite different from those of its constituents, or from those of the host metal, which is why alloying is carried out in the first place. For instance, zinc is added to copper to make brass, which is much stronger and more durable than either of its two constituents. Chromium and nickel are added to iron to make stainless steel, an alloy with greatly enhanced corrosion resistance. The hazard characteristics of an alloy can also be different from those of its constituents, due to chemical interaction within the alloy causing inhibition of subsequent release of the hazardous constituent. The hazard characteristics of an alloy can only be assessed properly by testing the alloy itself.

However, for certain important categories of classification, particularly carcinogenicity, the current EU rules for the classification of preparations do not allow testing of preparations. Instead, a classification is assigned via the ‘conventional’ method, which is based purely on how much of the hazardous constituent the preparation contains, even if there is no evidence for the hazard of the preparation itself. If an alloy contains 0.1% or more of a constituent that is classified as a Category 1 or 2 Carcinogen, then the alloy itself must also be classified as a Category 1 or 2 Carcinogen, regardless of the fact that there may be no evidence for such a classification. It is possible that some alloys, including copper beryllium (CuBe) alloys, are inappropriately classified as carcinogens under these rules. This background should be taken into account in the risk assessment of alloys.

1.3.1 COPPER BERYLLIUM ALLOY

This family of alloys represents by far the greatest use of beryllium. By weight, copper beryllium alloys typically consist of at least 98% copper, with up to 2% beryllium, plus small percentages of nickel or cobalt. The basic reason for their industrial importance is that they are very strong, up to around twice as strong as pure copper and as strong as many steels, and yet very electrically and thermally conductive, in the range 10-70% that of pure copper. This is an unusual combination. Most strong metals and alloys have much lower conductivity. For example, the conductivity of steel is in the range 5-10% that of copper.

These properties arise from the distribution of the beryllium atoms within the copper crystal structure. The alloys are what are known as age-hardening, or precipitation-hardening alloys. At very high temperatures, around 800-900°C, the beryllium content dissolves into the copper crystal structure and, by rapid cooling, this supersaturated ‘solid solution’ can be retained at room temperature. In this metastable state, the beryllium atoms are evenly dispersed throughout the crystal structure, and do not greatly change the properties of the copper, so the alloy is still relatively soft.

However, if the alloy is then reheated to around 300°C, and held there for about 2 hours, (this is ‘aging’, or ‘precipitation’ treatment) the beryllium atoms precipitate out of solid solution and form sub-microscopic particles of copper beryllide compound. These particles are still evenly distributed throughout the copper crystal structure, but they are now much bigger than the beryllium atoms, and they locally distort the copper crystal structure. If stress is applied to the alloy, the particles inhibit attempts by the copper crystal structure to deform to accommodate the stress. In other words, they stiffen the copper structure, making it stronger. The particles are still sub-microscopic, however, and still allow easy flow of electrons through the copper crystal structure, which is why the alloy retains a relatively high level of conductivity in spite of the marked strengthening effect. The alloys have the additional advantage that they are then able to resist the softening effect of any subsequent elevated temperatures which they might experience during application, having already been processed at around 300°C.

By adjusting the heat treatment conditions, as well as the beryllium content, the strength/conductivity combination can be optimised for the intended application. A further advantage of this type of alloy is that it can be easily formed into complex shapes while in the soft condition and the resulting component can then be strengthened by a simple aging heat treatment. Other high strength materials are often limited in the shapes that can be made from them, since they must be formed whilst already strong. For these reasons, copper beryllium alloys allow considerable freedom of design in complex and demanding EEE applications.

1.3.2 NICKEL BERYLLIUM ALLOYS

These alloys are similar to copper beryllium alloys, the difference being that the host metal of the alloy is nickel instead of copper, i.e. they consist of up to 98% nickel, with up to 2% beryllium. Once again, they are age-hardenable alloys, with the advantages of high strength, high elevated temperature relaxation resistance, reasonable conductivity and good formability. Their added advantages over the copper-based alloys are that they are more highly corrosion resistant and capable of withstanding much higher temperatures.

They find similar applications to copper beryllium, but are especially used for mechanical and electrical springs which must operate at elevated temperatures and/or in corrosive atmospheres, over long periods of time. Typical applications are found in oven controls, or fire detection and fire-fighting sprinkler systems.

Health and environmental issues associated with the supply and use of nickel beryllium alloys are broadly the same as for copper beryllium alloys, the exception being the additional potential hazards associated with nickel alloys.

1.4 BERYLLIUM OXIDE CERAMICS

Beryllium oxide ceramic is electrically non-conductive but is highly thermally conductive making it useful as a substrate for high-frequency, high powered integrated circuits. Beryllium oxide ceramic also possesses a Coefficient of Thermal Expansion (CTE) that closely matches Gallium Arsenide (GaAs). As an oxide ceramic, beryllium oxide is inherently stable in oxidizing environments and beryllium oxide ceramic possesses a mature metallization system making it the preferred material in applications where high reliability is required. In many cases, beryllium oxide ceramic is the only material that can provide the performance required by the application. Beryllium oxide ceramic requires no special handling in solid form.

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2. APPLICATIONS IN EEE

2.1 BERYLLIUM METAL AND COMPOSITES

Beryllium metal and composites are rarely used in consumer electrical and electronic equipment, due to its relative cost, and are not used in EEE applications which are dispersive to the environment. The metal is used as discrete components within certain specialized, high technology equipment, where it remains environmentally inert throughout its useful life. Broadly, the applications in EEE for the metal and composites divide into the categories listed below. Approximately 2 tonnes per year of beryllium are incorporated into these EEE applications in Europe.

2.1.1. Alternative energy research

Beryllium has played an important role in European efforts to develop controlled nuclear fusion energy systems, as a possible future alternative to the burning of fossil fuels, and is expected to continue to be of importance in the industrial development of such systems. This role is based upon its neutron reflecting and moderating properties, its ability to withstand high temperatures, and the fact that it does not contaminate the nuclear plasma energy source.

2.1.2. Particle physics research

Europe plays a leading role in efforts to understand the fundamental nature of matter, using evidence generated by the ultra-high speed collision of sub-atomic particles, to release still smaller particles and attendant radiation. Such work is carried out at the Organisation Europeenne pour la Recherche Nucleaire (Centre Europeenne pour la Recherche Nucleaire/CERN) in Switzerland, a world leader in this research. Because of its favourable nuclear properties, beryllium is often used to manufacture components for use in particle generation and detection equipment.

2.1.3. High speed rotational applications

A number of applications require components which are rotated at high speed and which may also be subject to rapid acceleration and deceleration. Examples of such applications include the rotational parts of inertial guidance systems, ultra-high speed camera mirrors, optical scanning devices and tool spindles for drilling equipment used, for instance, in automated printed circuit board production. Accurate operation of such equipment requires the rotating components not only to be capable of rapid acceleration and deceleration, requiring low mass, but also to be capable of resisting deformation under the high rotational stresses involved, i.e. high rigidity. The exceptional specific rigidity of beryllium makes it the ideal material for such applications.

2.1.4. Medical equipment

Beryllium is highly transparent to X-rays. For that reason it is used as a window material in X-ray emission and detection equipment. Such windows need to be made from extremely thin foil, to further enhance transparency, but also need to be strong enough to withstand external atmospheric pressure against the vacuum inside the equipment. They also need to be bonded into their metallic housings by high temperature brazing, so that the seal can withstand the heat generated by the X-ray source. The combination of properties offered by beryllium make the metal uniquely suitable for this application. It finds use in a wide variety of X-ray equipment, including security systems and medical equipment, for instance in mammography, where resolution of fine detail in the X-ray image is essential.

2.1.5. Military targeting and guidance systems

Modern defence systems rely heavily on sophisticated electronic equipment for navigation as well as for target acquisition and firing mechanisms. Usually, and especially for aircraft-mounted systems, such equipment needs to be lightweight but rigid, in order to provide precise operation under extreme conditions. The properties of beryllium are ideal for such purposes. It will be used, for instance, in the targeting systems on the Eurofighter. It is also used for the targeting mirror on the German Leopard tank.

2.2 BERYLLIUM-CONTAINING ALLOYS

The vast majority of applications involve the use of massive copper beryllium components, which are inert, stable, and do not give off emissions during use. In EEE, these applications broadly divide into the following categories. Approximately 11.5 tonnes per year of beryllium from beryllium-containing alloys are incorporated into these EEE applications in Europe. Additionally, only a small amount of beryllium ends up in the final product. For example, among EEE applications that use beryllium-containing alloys, cellular phones typically contain the most beryllium at approximately 40 ppm (0.004% by weight)[6], yet the impact on performance is substantial. Beryllium-containing alloys are only used in key places in EEE where they provide a design solution based on miniaturization, improved energy management, reliability and/or extending the service life.

2.2.1. Electrical contacts and connectors

Applications within this category comprise by far the largest use of copper beryllium alloys (and hence by far the largest use of beryllium). Copper beryllium connectors are found in a wide range of electrical equipment, including telecommunication systems, computers and industrial and medical controls.

Electrical circuits are only as reliable as their connections allow them to be, and connection failure is one of the greatest causes of electrical breakdown. Such failure must clearly be avoided, especially in critical circuitry upon which the safe operation of equipment depends. Connector design and the choice of connector material greatly influence connector reliability.

Connector materials must obviously be good electrical conductors, to be able to deliver the electrical power or signal. They must also be strong enough to grip or press upon mating components, in order to ensure good mechanical contact at all times, sometimes whilst enduring vibrational stresses, or after repeated making and breaking of the connection. They must be able to maintain their grip, or spring force, over long periods of time, sometimes at elevated temperatures which tend to gradually weaken connectors. They must be corrosion resistant, to prevent loss of surface conductivity. They must allow the manufacture of complex and often miniaturised connector shapes.

Almost all electrical connectors are based on copper, because of the high conductivity offered by this metal. For most connectors, however, the copper must be strengthened in order to achieve the required spring force in the connector, and this is generally done by a combination of alloying and ‘cold work’, e.g. cold rolling the material, which makes it harder. Cold rolled brasses (copper plus zinc) and bronzes (copper plus tin) are common materials used for less critical connectors. However, both alloying and cold working, while increasing strength, generally tend to reduce conductivity significantly. For example, brasses and bronzes have conductivities only as high as 10-15% that of copper. Cold working and alloying also reduce formability, limiting the shapes that can be made from the alloy. Furthermore, cold worked metals and alloys tend to suffer marked strength reduction after prolonged exposure to elevated temperatures as the heat ‘relaxes’ the cold work stresses out of the crystal structure, which is obviously a matter of concern for connectors which must operate in hot environments.

Copper beryllium alloys are far less susceptible to these adverse effects and offer the connector designer the highest strength, the highest conductivity, the greatest elevated temperature stress relaxation resistance and the greatest formability of any of the copper alloys. For critical connections in circuitry where the highest performance and the greatest reliability are of paramount importance, the superior properties of copper beryllium alloys are considered to be vital.

2.2.2. Electromagnetic radiation shielding

An important requirement for many electrical circuits is that they are shielded against electromagnetic radiation emanating from other sources, which could interfere with the functioning of the circuit, or to prevent such radiation which they themselves generate from causing such interference in other circuits. Shielding often consists of metal enclosures which, for mechanical and electrical contact reasons, need to be strong. They also need to have good electrical conductivity, especially when shielding against high frequency radiation. Once again, copper beryllium is an ideal material for this type of application.

2.2.3. Miniaturization

Design of electrical equipment frequently requires miniaturization of components, including connectors, to decrease overall size or weight and to get higher performance capability into the product. However, this must not be achieved by sacrificing connector reliability. Miniaturized connectors still need to have sufficient strength and conductivity to perform their function reliably, even though both of these properties are reduced as the dimensions of the connector reduce. Under these circumstances, the unique property combinations offered by copper beryllium become extremely valuable to the designer. The superior strength, conductivity and relaxation resistance of these alloys allow smaller connectors to be made, with dimensions at which connectors made from other alloys would become unreliable, especially if the connector has to perform at elevated temperature. It should also be noted that miniaturization brings environmental benefits, as well as design benefits. Less material is used, with proportionate reduction in energy use and environmental impact from the alloy production process. Furthermore, less energy is generally needed to operate miniaturized equipment.

To give some idea of material savings which can be achieved by using copper beryllium alloy, compared to some other common connector alloys, dimensional calculations have been made for a theoretical connector required to deliver a given spring force at elevated temperature over a prolonged period. In this calculation, it was found that a copper beryllium connector could be made which would require only one quarter of the weight of alloy which would be required if the connector were made from phosphor bronze, another common connector material.

None of the above applications involve health or environmental risks. The copper beryllium components remain solid and inert throughout their useful lifetime.

2.3 BERYLLIUM OXIDE CERAMICS

Beryllium oxide ceramic is rarely used in consumer electrical and electronic equipment, due to its higher relative cost, and are not used in EEE applications which are dispersive to the environment. Beryllium oxide ceramic is used in components for high reliability, high technology equipment, where it remains environmentally inert throughout its useful life. Broadly, the applications in EEE for beryllium oxide ceramic divide into the categories listed below. Approximately 1.5 tonnes per year of beryllium oxide are incorporated into these EEE applications in Europe.

2.3.1. Photonics/Laser Applications

Noble gas Ion lasers (i.e. Argon), are typically found in applications requiring precise, continuous, beams, such as medical and semi-conductor inspection equipment. Gas lasers require a low voltage, high current discharge to create the population inversion. The high-power for the discharge is deposited on the laser head as heat which must be removed from the system. Electrical current densities in the bore are also very high and place large stresses on the materials.

All air cooled noble gas lasers use beryllium oxide ceramic for the laser bore due to the high thermal conductivity (TC) of the material. Beryllium oxide ceramic is the only material that offers the combination of thermal conductivity, strength, and the dielectric properties required by the application. The material has low porosity, is not brittle and resists erosion, which is a failure mode of the gas laser. Beryllium oxide ceramics also holds up mechanically during the manufacturing process and the thermal conductivity allows the bores to handle the brazing cycles during assembly. The beryllium oxide ceramic laser bore also contains the beam and provides for gas return.

In the medical field, gas laser applications include DNA sequencing, Flow Cytometry, and hematology. Industrial applications include semi-conductor wafer scanning. No other technology, including solid state lasers, can currently produce the continuous blue 488-nm beam required in many medical applications.

In newer technologies, such as solid state lasers and light emitting diodes (LED), beryllium oxide ceramic’s electrical isolation, high thermal conductivity and CTE match with GaAs has made it the material of choice in the high powered applications such as lasers for machining and welding.

2.3.2. Solar Energy – Concentrated Photovoltaic Cells (CPV)

A new technology, call concentrated photovoltaic (CPV), is being developed and used to effectively generate electricity. The new CPV technology is a major efficiency improvement over standard thin film and other silicon photovoltaics. While traditional photovoltaic cells and newer thin film cells are less than 10% efficient, CPV's are approaching 30% efficiency, and could get to as high as 40%. The new CPV’s also don’t require silicon, the main cost driver in today’s solar market. This lowers the cost per watt and allow CPV’s to become a viable alternative to fossil fuel power plants. Current targets for CPV's are to produce a kilowatt for approximately ten cents - versus standard solar panels that run about 30 cents a kilowatt. In addition, because CPV’s are so efficient, the area required for installation is also reduced, saving valuable real estate. Several development efforts are in process, notably a 500kW trial installation in Puertollano, Spain. By 2009, a 15 megawatt site is currently planned. A coal fired power plant uses 1 pound of coal, 1/2 gallon of water and releases 2 pounds of CO_2 to generate one kilowatt of electricity. All of these environmental costs are avoided with CPV's.

CPV's often are subjected to power equivalent to 500 suns and thus face intense heat. Dissipation of heat and long term reliability requirements were the major obstacle preventing the success of early CPV’s. Once installed, a CPV needs to survive 20-30 years in a harsh environment like the Arizona desert where it will face large variations in temperature and humidity. Beryllium oxide ceramic has a long history of service in applications that demand the highest reliability under the most demanding conditions. Compared to alternative material configurations, beryllium oxide ceramic has better shock resistance, higher thermal conductivity and a Coefficient of Thermal Expansion (CTE) that is more closely matched to the GaAs and germanium in the solar cell. Beryllium oxide ceramic also has mature metallization systems that have been proven reliable in oxidizing environments, unlike other high TC ceramics, such as Aluminum Nitride (AlN), which are not stable in moisture containing air. Finally, when compared with alumina, beryllium oxide ceramics is approximately eleven times more shock resistant. As a result of the inherent, superior properties, multiple development efforts, in addition to the Puertollano, Spain installation, are currently underway for beryllium oxide ceramics, and it is likely that it will prove to be the only viable solution in the long term.

2.3.3. Radio Frequency (RF) Applications

The combination of electrical isolation and high thermal conductivity has led to a wide variety of applications in the RF markets. Beryllium oxide ceramic products can be found in high power, high frequency applications such as wireless base stations, radar, and high-powered microwave transmitters, such as travelling wave tubes (TWT).

TWT power tubes are preferred for applications requiring both higher frequency and higher power. TWT’s are found in application areas such as radar, electronic counter-measures, ground terminals, microwave instrumentation and in space applications, including scientific experiments and communication applications. Higher powered TWT’s often contain beryllium oxide ceramic as both a helix support rod and in some cases, as an electron collector for the TWT. Beryllium oxide ceramic is used because of its electrical isolation properties and thermal conductivity. In addition, unlike alternative materials, such as pyrolytic boron nitride which is isotropic, beryllium oxide ceramic conducts heat in all directions. Finally, beryllium oxide ceramic offers superior mechanical properties. As advancements in TWT technology have continued to drive the size and tolerances of T-rods ever smaller, designers need a material that can ensure that ceramic components survive the manufacturing process.

For similar reasons, beryllium oxide ceramic’s thermal, electrical and highly developed metallization system make it the material of choice versus aluminum nitride (AlN) in telecommunication applications such as resistors, amplifiers, terminations, attenuators and collectors.

2.3.4. Power Electronics

Because of beryllium oxide ceramic’s high thermal conductivity and low dielectric, a semiconductor package utilizing beryllium oxide ceramics offers higher power bandwidth and lower losses and distortion necessary for more efficient motor speed control or position control. Applications also include Piezo drives for precision control in pick and place applications or in high speed printing. In today’s world, beryllium oxide ceramics enable designers to satisfy customer’s ever-increasing demand for more power and precision.

2.3.5. Medical Applications

The use of beryllium oxide ceramics in medical technology is critical for both the diagnostic and treatment sectors of the industry as it provides superior performance and reliability in high temperatures or high frequency applications, applications where material failure is unacceptable. Beryllium oxide ceramic is a critical component in equipment that is used as a source of hard X-rays and high-energy electron beams that drive X-ray devices in medical diagnostic equipment. This equipment is used in Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scanners to provide high resolution diagnostic imagery. New applications for beryllium oxide ceramic can also be found in such critical life-saving technologies as portable defibrillator machines.

3. HEALTH ASPECTS

3.1. Classification

In the EU classification system, beryllium metal is classified within the generic grouping 'Beryllium and beryllium compounds'. This grouping includes commonly used, environmentally inert, insoluble materials, i.e. the metal, the oxide and its alloys, together with chemically active, water-soluble beryllium salts, such as beryllium fluoride, beryllium sulphate, etc. which are rarely encountered outside of analytical laboratories and not present in EEE. Within this generic grouping, hazards associated with the active compounds have been attributed automatically to the inert materials, in some cases inappropriately.

Alloys are categorized as preparations for classification purpose, so copper beryllium alloys are classified according to the 'conventional' method specified in the Preparations Directive, i.e. based simply on the classification of beryllium and how much beryllium the alloy contains.

As is the case for beryllium metal, the only significant hazard actually associated with the alloys and ceramics is the respiratory hazard, CBD and risk can only arise if airborne respirable particulate is generated during processing.

3.2. Chronic Beryllium Disease (CBD)

This respiratory disease, associated with inhalation of airborne beryllium-containing dust, mist and fume, was recognised more than fifty years ago. There is no inhalation risk associated with the massive forms in which the metal, alloys and ceramics are used.

In order to contract CBD, an individual must be exposed to airborne beryllium in the form of a dust, mist or fume. This particulate must be small enough to reach the air sacs deep in the lungs and the individual must be sensitive to beryllium. Not all individuals exposed to airborne beryllium particulate will become sensitised and of those who become sensitised, not all will develop CBD[7]. Scientists believe that the capacity to develop sensitivity to beryllium is genetically determined[8] and that most people are not susceptible to becoming sensitized. Today's definition of beryllium sensitivity is not considered a health effect.

Before the late 1980s, workers were diagnosed with CBD only when they exhibited clinical (observable) symptoms of CBD and changes in their chest X-ray or lung function test. Symptoms could include unexplained dry cough; shortness of breath, especially with activity; and fatigue. During the late 1980s and early 1990s, the criteria by which CBD was diagnosed changed, and workers began to be diagnosed with CBD without clinical symptoms or measurable impairment. This diagnosis became possible as a result of the application of new technology in medical testing and evaluation. Workers diagnosed with CBD in the absence of X-ray or lung function changes or symptoms of disease are referred to as having sub-clinical CBD, meaning that they have no clinical symptoms or measurable impairment. These workers are typically diagnosed based on sensitisation and the presence, upon biopsy, of microscopic biological lung formations called granuloma. Workers with subclinical CBD may never develop clinical CBD or may develop clinical CBD over time. The only countries using these expanded definitions of CBD, are the United States and a single province in Canada. Most countries do not recognize subclinical CBD as disease.

For situations where risk of inhalation exposure exists, an airborne standard was developed in the U.S.A. in the late 1940s that was generally adopted internationally and is still used today. This standard is 2 micrograms beryllium per cubic meter of air (2 $\mu g/m^3$), time-weight averaged over an 8-hour work period. Research has demonstrated this standard to be effective in preventing clinical CBD[9].

Though manufacturing of alloys has been associated with CBD, it is clear from the literature that every published epidemiological study involving alloys which has resulted in CBD has involved melting, hot forming, heat treating, or chemical cleaning (acid or caustic pickling) operations. Furthermore, oxides of beryllium can be released to the air during subsequent material handling operations and during surface oxide removal steps such as mechanical cleaning (brushing, grinding, polishing) or via pickling with acid or caustic solutions. For beryllium-containing alloys, an absence of exposure to loose surface oxides containing beryllium suggests a lower risk of developing CBD. Hoover[22] found no cases of CBD diagnosed among machinists working exclusively with clean beryllium-containing alloys. Copper beryllium alloys are supplied and most commonly handled and formed as clean metal without loose surface oxides. The potential for exposure to airborne beryllium from machining of beryllium metal is significantly greater than from machining of alloys due to their significant metallurgical differences. In simple terms, when machined, beryllium metal tends to fracture and generate small particulate while alloys break into large chip with little to no fine particulate.

Current research is focusing on identifying the potential pathways for exposure and causes of CBD. Findings from this research indicate that a high level of compliance with the 2 $\mu g/m^3$ standard can be protective at preventing clinical CBD, but not necessarily protective at preventing sensitization or subclinical CBD. These findings also indicate that chemical form[10], particle size and number[11], and specific processes[12] can affect work-related risk. Findings indicate that the use of engineering and work practice controls have been effective at preventing sensitization, sub-clinical CBD and clinical CBD[13]. These findings raise questions as to which health outcome (sensitivity to beryllium, subclinical CBD or clinical CBD) should be used to establish worker protection levels and whether the current methods used to measure compliance with the occupational standard are the best way for measuring potential risk to the worker. Research and evaluation is continuing to answer these questions.

Based on the available information, Brush Wellman, the leading international supplier of high performance engineered materials containing beryllium, has adopted a recommended exposure guideline for airborne beryllium of 0.2 $\mu g/m^3$ as an 8-hour time-weighted average.

3.3. Carcinogenicity

The carcinogenic risk associated with beryllium is by no means certain and recent studies strongly support a reclassification of beryllium as non-carcinogenic in humans. For purposes of risk analysis, it is necessary to be aware that the evidence for carcinogenicity which led to the current classification for beryllium has not been formally reviewed in over 15 years. Recent studies, which will be discussed below, have shed light on the question of beryllium carcinogenicity and have concluded that beryllium is not carcinogenic in humans or may at worst be an extremely weak carcinogen under conditions of massive airborne exposure levels not encountered since the 1940's.

Epidemiology Studies

The claim for human carcinogenicity is based primarily on an epidemiological study[14] carried out by the U.S. National Institute for Occupational Safety and Health (NIOSH). This 1992 study by Ward et.al. reviewed the mortality records of over 9,000 people who worked in the beryllium industry at seven different facilities between 1940 and 1969. Across the whole of this cohort, after correction for smoking, NIOSH found a Standard Mortality Ratio (SMR) of 1.12. This SMR is not high enough to indicate a statistical link between cancer and beryllium exposure because the 95% statistical confidence interval overlaps unity (0.99-1.26).

Analysis of the data for each individual facility showed that only the oldest facility produced a statistically significant SMR of 1.49 after correcting for smoking. Though, statistically significant for this single plant, in statistical terms, this is still a very low SMR, less than one tenth of the SMR ascribed to passive smoking. Yet some in the scientific community have inappropriately selected the cancer risk data from this single plant to assign a cancer classification to beryllium. This selective use of data dilutes the statistical power provided by the much larger seven plant population as a whole. It is more appropriate to use the multiple plant data to draw conclusions of carcinogenic risks. In fact, the authors of the study were not definitive in their conclusion that *"occupational exposure to beryllium compounds is the most plausible explanation for the increased risk of lung cancer observed in the study."*

This use of the NIOSH study conclusion as definitive evidence of beryllium carcinogenicity has been the subject of significant debate among medical scientists and statisticians ever since it was published in 1992. The essential features of the debate are claims that the NIOSH analysis did not compare cancer incidence in the exposed population with that found in relevant, non-exposed populations, using rural, rather than urban rates; that the NIOSH smoking adjustment was inadequate, and that there were errors in the calculations and conclusions which NIOSH drew from the data. Several re-analyses of the same data have concluded that there is no clear statistical link between lung cancer and beryllium exposure.

A major reanalysis of the same NIOSH data used in the Ward study, using more sophisticated methods to adjust for smoking, calculate appropriate expected lung cancer rates, and perform meta-analysis on the data was published by Levy et al in 2002[15]. The Levy 2002 study clearly illustrates that simply replacing the smoking adjustments used in the Ward study with other commonly accepted smoking adjustments results in a data analysis which varies between statistical significance and non-significance. Ward studied seven beryllium plants but found only one of seven plants had a statistically significant cancer risk after adjusting for smoking. Levy evaluated the same data for this single plant using two different smoking models. Levy found the U.S. Veterans model showed a lower yet still significant risk while the Wagoner model showed no significant risk. The use of common statistical smoking adjustments which result in standard mortality ratios which vary between statistical significance and non-significance demonstrates the fragility of the Ward analysis and does not provide reasonable evidence of known carcinogenic risk.

Levy also performed an analysis on the at-risk plant using a combined city-county cancer rate versus the county-wide cancer rate used by Ward. Levy included city rates because most of the workers lived in the city versus the surrounding rural countryside. Levy utilized a weighted average of combined city/county rates based on the percentage of workers living in the city plus the percentage of workers not living in the city. This is particularly important because the largest industry in the city in which the Lorain plant was located was steel making (ore through final product) during the time this plant existed in the 1940s. Ward's use of the cancer rate for the entire county dilutes the cancer risk by disproportionately including those persons living in rural areas away from pollutants in the city. Therefore, Levy's methodology is a more accurate estimate of the referent rate.

Levy's comparison to a weighted city/rural referent rate resulted in a non-significant statistical cancer risk at this plant without even considering smoking risks. Levy's finding demonstrates that minor differences in the referent population used to estimate cancer risk can easily move the beryllium cancer risk estimate in and out of statistical significance. Again, this low statistical confidence does not provide reasonable evidence to support a known human carcinogen cancer classification for beryllium. Dr. Levy concluded: *"there is no statistical association between beryllium exposure in these workers and lung cancer when using the most appropriate population cancer rates."*

In 1991, the UK Health and Safety Executive conducted a thorough review of beryllium carcinogenic risks, including animal data, and stated *"…. no conclusions can be reached…. regarding the carcinogenic potential of beryllium in humans".* In 1994, Brian MacMahon[16], MD, Head of Epidemiology at Harvard School of Public Health, concluded, in relation to the NIOSH study, that *"…confounding by cigarette smoking is a more likely explanation of the lung cancer excess than is occupational exposure to beryllium compounds"*. In 1999, Dimitrios Trichopoulos[17], Director of International Research, Harvard Center for Cancer Prevention, also reviewed the NIOSH data and commented that *"The evidence for human carcinogenicity from even extreme concentrations of beryllium is the weakest ever advanced for any compound that has been characterised as a human carcinogen".*

A study by Sanderson in 2001 of beryllium employees at the Reading, Pennsylvania facility was undertaken to evaluate the association between beryllium exposure and lung cancer[18]. The Sanderson cohort-nested case control study exploring the relationship between beryllium exposure and lung cancer found workers who developed lung cancer to have worked fewer days and to have no higher cumulative, average or maximum beryllium exposure than other workers. However when exposure was truncated (lagged) with lung cancer latency assumptions of 10 and 20 years, workers who developed lung cancer had higher lagged values for all four exposure metrics. The higher lagged exposure in cases was interpreted by Sanderson as indicating that beryllium exposure caused lung cancer.

Recent studies by Levy 2007 and Deubner 2007 are particularly relevant in the evaluation of whether cancer risk can be estimated for various exposure levels. These studies confirm that Sanderson 2001 contains a serious methodological artifact which invalidates the conclusions of Sanderson. Levy 2007 provides a reanalysis of the Sanderson study which demonstrates that when the artifact is corrected, the conclusion is that the lung cancer in this population was not associated at all with beryllium exposure, whether defined as time worked, or cumulative, average or maximum exposure. Deubner 2007 confirms the methodological artifact identified by Levy using repeated data simulations.

Deubner applied the index study design to a closely related cohort using randomly selected probands as cases. Values for average exposures were assigned to probands equal to, greater than, and less than those assigned to controls (matches). He found that under certain lag scenarios the nested study design produced a finding of higher average exposure in probands compared to their matches even when this was clearly not the case. The empirical evaluation demonstrated that the study design produced a biased case-control lagged exposure difference under the null hypothesis in the direction of higher lagged exposure for cases compared to controls. Also, the study design could not distinguish qualitatively between null and alternate hypotheses. The reason for this bias was that the Sanderson study design selected controls with significantly higher *ages at hire* than cases. When exposure was lagged, the older *age at hire* of controls caused a higher proportion to "lag to zero", an effect magnified by the log transformation of the exposure variables.

Deubner's analysis determined that the Sanderson study finding was due to a methods artifact that is correctable by closer matching of controls to cases. With the artifact corrected lung cancer cases had no higher exposure than controls whether exposure was unlagged or lagged, suggesting that lung cancer in these beryllium workers was not caused by their exposure to beryllium. Published concurrently with Deubner 2007 is an editorial by Dr. Garabrant commenting on the significance of Deubner's finding and cautioning that other epidemiological studies may be subject to the same methodological flaw[19].

One approach to control the artifact was performed by Levy 2007, who compared the lung cancer cases to the controls with the closest ages at censor. With the artifact thus controlled, there were no differences in lagged or unlagged exposure. This established with dose reconstruction what was suspected from Ward 1992 and earlier studies[20], that lung cancer in beryllium workers is not associated with the degree of exposure to beryllium.

Levy 2007 also reduced the case control difference in age at hire by using controls closely matched to cases, and did not log-transform the exposure data. This reanalysis found no elevated odds ratios for any of the exposure variables: time worked in a beryllium manufacturing facility, or cumulative, average or maximum beryllium exposure. Therefore, Levy found no causal relationship between beryllium exposure and lung cancer.

A 2004 study by Brown et al.[21] identified a cohort of 16,303 production era workers employed at the Rocky Flat Plant for six months or more between 1952 and 1989. This is a very important study because it is the first to use a study cohort different than that used for every other beryllium cancer study. For this cohort, a job exposure matrix was used to estimate exposures to various chemicals including beryllium. The fabrication of plutonium pits was the primary production activity at Rocky Flats and beryllium was used in the production of the pits. The Rocky Flats Beryllium Health Surveillance Program (BHSP) database, containing 23,196 records, was obtained. The BHSP was a Department of Energy effort to identify and contact all current and former employees of the DOE at Rocky Flats, its prime contractors and subcontractors to obtain information about exposure to beryllium and evaluate each for signs of beryllium disease. For beryllium, exposure estimates were made from a few hundred air samples collected during production era activities. Annual exposure estimates for each worker were generated by linking workers to a job exposure matrix developed from monthly job and building assignments from 1951 to1989. Historical records of chemical usage were reviewed and a list of job titles and organizational names was developed. In person interviews were conducted with persons who held jobs having an exposure potential to document the tasks performed by each job title, the materials used, and to identify jobs with similar exposures.

The study concluded: "*No associations were found between lung cancer mortality and cumulative external penetrating radiation dose or cumulative exposures to asbestos, beryllium, hexavalent chromium, or nickel.*"

These above beryllium studies deal with sizeable cohorts exposed to very high levels of beryllium. Failure to find convincing evidence that beryllium workers have excess rates, combined with clear evidence that in beryllium workers lung cancer is not related to degree of exposure, strongly supports a reclassification of beryllium as non-carcinogenic in humans.

It should be stressed that this debate is solely concerned with the marginally significant data from the oldest of the seven United States facilities, which ceased operation in 1949, with no cancer-beryllium link in the other six facilities. The International Agency for Cancer Research[22] (IARC) has noted that workers in this oldest plant were exposed to airborne beryllium levels around 1000 µg/m³ Be air, whereas the beryllium industry and its customers have worked to a safety standard of 2 µg/m³ Be air for the past 50 years. Furthermore, workers in that oldest facility were exposed to a mixture of chemicals, including sulphuric acid mist[23], an identified human carcinogen[24], which was not taken into account in the NIOSH study. These points underline the fact that the incidence of cancer, even under extreme and confounded conditions, was still so low that scientists cannot agree that a link with beryllium exposure was proven.

Animal Studies

In the 1950s and 60s, several animal studies were made, using intra-tracheal or inhalation exposure to beryllium compounds, producing some evidence for carcinogenicity in rats, but not in rabbits, hamsters, or guinea pigs. Monkey evidence was poorly controlled, and mixed. Once again, the evidence for carcinogenicity is not entirely clear, and is subject to scientific debate. In 1987, Dr Andrew Reeves, of the Department of Occupational and Environmental Health, Wayne State University, Detroit, conducted a review of all such work, and concluded *"…. closer examination of these animal data raises serious questions about their applicability to human carcinogenicity. The early animal studies, while voluminous, were, for the most part poorly conducted, incompletely reported, and would be unacceptable by today's scientific standards"*.

The United States Environmental Protection Agency, after making an evaluation of the animal studies similar to that made by Dr. Reeves, states:

> *"With the possible exception of the Wagoner et al (1969) study, the results of the animal carcinogenicity studies are incompletely reported and are not of sufficient quality to be used as the basis of quantitative cancer risk estimates. Because Wagoner et al (1969) exposed the rats to ores with relatively low beryllium levels and high levels of silicon dioxide, this study would not be an appropriate basis for a risk estimate for general population exposure to beryllium."*

Within the EU scientific community, the reliability of the data is a key initial consideration to filter out unreliable studies followed by a closer evaluation of those studies considered most reliable. Without knowledge of how a study was conducted, all other considerations may be irrelevant. An approach used in Europe to assist the initial screening of study reports to set aside unreliable studies is that developed by Klimisch et al. (1997)[25]. Those studies receiving a Klimisch rating of 1 or 2 are considered adequate to support data assessment needs. This approach was developed as a scoring system for reliability as follows:

1 = reliable without restrictions: "studies or data generated according to generally valid international and/or Organisation for Economic Co-Operation and Development (OECD) accepted testing guidelines, which were conducted using Good Laboratory Practices (GLP) and for which test parameters are complete and well documented."

2 = reliable with restrictions: "studies or data (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which

cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."

3 = not reliable: "studies or data in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., unphysiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment."

4 = not assignable: "studies or data which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)."

A search strategy of relevant data bases was developed for the literature search and the results for beryllium produced 1531 hits after non-relevant articles were discarded. Among these hits, 775 hits were provided with an abstract. Abstracts and all other cells were searched for the key words "Tox*, Mutagen*, Genotox*, Carcinogen*, Reprod*, Irrit*". Results comprised 517 hits are broken down according to organisms and key words used in the following table. (Individual hits may be assigned to more than one key word.)

Key word	**Hit**	**Electronic file**
Cells	93	,,BerrylliumMitAbstractsToxCells_93.rtf"
Animals	209	,,BerrylliumMitAbstractsToxAnimals_209.rtf"
Humans	159	,,BerrylliumMitAbstractsToxHumans_159.rtf"
Genotox*	27	,,BerrylliumMitAbstractsToxGenotox_27.rtf"
Mutagen*	35	,,BerrylliumMitAbstractsToxMutagen_35.rtf"
Carcinogen*	141	,,BerrylliumMitAbstractsToxCarcinogen_141.rtf"
Reproductive toxicity	1	,,BerrylliumMitAbstractsToxReprod_1.rtf"
Irritant	4	,,BerrylliumMitAbstractsToxIrritant_4.rtf"

The 756 hits, not provided with an abstract, were mainly older publications and did not conform to the search guideline. In order not to miss any hits, information given was also screened with the same key words as listed above that were channeled in the further evaluation. In summary 138 publications were examined according to the Klimisch system and 100 publications which could be evaluated and therefore ranked Klimisch 3 or better (of which 64 hits provide in-vivo data and 36 hits provide in-vitro data). The rest of the papers were either quoted in reviews or were published as abstracts. The documentation of experimental details, including verification of chamber exposure concentration values, is unavailable. These data were appropriately considered as not assignable (Klimisch Rating: 4).

Summary of Literature Review Animal Studies

It must be again stated that most, if not all of the animal and in-vitro studies do not comply with modern requirements of study conditions, e.g. described in OECD Guidelines. None of these studies were conducted according to GLP, in particular many of the older studies do not have an appropriate control group or the study conditions and/or results are not adequately reported. Thus, the reliability of many studies was rated in accordance with Klimisch as not reliable (Rating 3) or not assignable (Rating 4). Ninety percent (90%) of the studies were performed using soluble beryllium compounds with a few performed using beryllium metal. No carcinogen studies were performed using copper beryllium alloys. Data and quality of animal studies are generally poor. For pure beryllium metal, there are only five (5) studies with Klimisch rating of 2 suggesting carcinogenicity of beryllium metal to rats and some strains of mice. However, the association is weak or non-existent in mice.

It appears that the induction of pulmonary cancer by beryllium metal and beryllium compounds is species-specific. While rats are susceptible, no pulmonary tumors were observed in some mice, rabbits, hamsters, and guinea-pigs. The latter were exposed to concentrations that were carcinogenic in up to 100% of exposed rats. The reasons for this negative neoplastic response are not known. According to Dr. Gregory Finch, it is has been suggested that the long-term chronic-active inflammation in rat lung, with relatively strong neutrophilic "foreign body-type" response, is sufficient to lead to neoplasms. This is a common occurrence in rat studies. There is no evidence for a carcinogenic action by beryllium and its compounds via the oral route.

In-vivo Animal Studies

Since about 1950, a series of studies on the carcinogenicity of beryllium and its compounds have been conducted. Most of these studies investigated the inhalation route because this route appears to be the most relevant for humans in workplaces.

Among the literature reviewed, 9 carcinogenicity studies were identified that are specific to beryllium metal and beryllium-containing alloys. Only the studies by Benson, et al., 2000[26]; Finch et al., 1996[27] & 1998[28]; Haley et. al., 1990[29]; and Nikula et al., 1997[30] can be classified as Klimisch Rating 2 (reliable with restrictions). The study by Benson did not assess carcinogenicity. The remaining studies demonstrate that there is carcinogenic evidence in rats and weak to non-existing responses in mice. This observation was also documented by Finch and Hoover who compiled (History of the LRRI Beryllium Research Program, August 1999) in a document “Overview and Publications of the Lovelace Respiratory Research Institute Beryllium Respiratory Research Program.” The investigating staff at the Lovelace Institute was comprised of Belinsky, Benson, Finch, Hoover, and Nikula whose studies were evaluated in this study. The authors stated:

> *“In 1987 our beryllium research program was expanded to include carcinogenicity studies in rats inhaling beryllium metal, especially when combined with an inhaled radionuclide such as plutonium. Published reports by other workers on the issue of beryllium carcinogenicity are contradictory, plagued with experimental design problems and inconclusive for predicting carcinogenicity of beryllium in humans. An additional factor has been the controversy surrounding the cancer epidemiology studies in beryllium workers. Our results demonstrated that inhaled beryllium metal is a potent lung carcinogen in rats. We subsequently extended these studies to mice to further our understanding of beryllium-induced carcinogenic process, and relevance to humans. Results indicate beryllium metal at similar lung burdens is not a pulmonary carcinogen to C3H mice and is weak in A/J mice.”*

The disconnect between carcinogenicity in the rat (the robust response at relatively low lung burdens) versus the weak to non-existing response in mice (A/J, C3H, and the p53 +/- TGs) may be explained that the long-term chronic-active inflammation in rat lung, with relatively strong neutrophilic "foreign body-type" response, is sufficient to lead to neoplasms. This has been observed with materials other than beryllium.

Laboratory animals, such as guinea pigs and rabbits do not appear to be sensitive to a carcinogenic action of beryllium and its compounds. Two inhalation studies on monkeys have shown positive findings, however, the studies are suspect as monkeys in one study were previously used in a smoking study and the other study suffered from a too small number of animals. Moreover, it should be noted that a study of inhaled beryllium oxide in Stumptail monkeys by Connradi 1971[31] yielded no observable pathology. It must be noted these studies were deemed to be unreliable when evaluated via the Klimisch assessment methodology.

As stated earlier, the carcinogenicity of beryllium is not certain and recent studies strongly support a reclassification of beryllium as non-carcinogenic in humans. However, it is clear that neither the human nor the animal data suggest no more than the possibility of very weak carcinogenicity under conditions of massive exposure. In fact, IARC has found reason to re-evaluate their classification of beryllium. Additional testing will be performed to meet the end points identified by the REACH Directive.

3.4. Ingestion effects

Beryllium is classified as toxic by ingestion, but there is no evidence to support this classification for beryllium metal and composites, beryllium-containing alloys or beryllium oxide ceramics.

There are no known studies regarding human ingestion of beryllium. There have been some animal feeding studies, which use soluble beryllium compounds. However, exposure to soluble forms of beryllium in industry is rare and is not known to occur in the general population. In addition, soluble forms of beryllium are generally not found in nature. The use of soluble beryllium compounds is largely an intermediate material confined to operations in the primary chemical extraction of beryllium and are not used in EEE. There are only two or three such operations in the entire world. In general industry, soluble beryllium compounds have limited use as analytical standards for chemical analysis in the laboratory and on rare occasions are used in research.

There have been two primary feeding studies involving beryllium. The Schroeder and Mitchener[32] study concluded that beryllium was *"virtually innocuous"* by ingestion and is not tumorogenic. Indeed, *"beryllium was noted for its lack of toxicity,"* and the authors concurred with previous studies indicating *"that beryllium is poorly absorbed through the gut, and that ingestion is not a hazard."*

The basis for the current classification of beryllium as toxic via ingestion is an interpretation of the table in the Morgareidge[33] dog study addendum which identifies “gastrointestinal lesions” as the end point. The beryllium compound fed to the dogs, in this study, was beryllium sulphate.

The only health effect noted in this study, even at high concentrations, is gastrointestinal lesions. This should be of no surprise since the commercial form of beryllium sulphate has a pH of 1, meaning it is highly corrosive. As a sulphated compound, the corrosive nature alone can account for the gastrointestinal lesions. It is illogical to implicate beryllium as the source of toxicity under such circumstances.

In summary,

- beryllium is poorly absorbed in the gut;
- feeding studies have not conclusively shown that any form of beryllium poses an ingestion risk due to beryllium;

- there are no known cases of beryllium-related ingestion health problems amongst beryllium workers; and,
- beryllium metal has never been implicated as an ingestion hazard.

3.5. Eye effects

There is no special eye hazard associated with beryllium metal and composites, beryllium-containing alloys or beryllium oxide ceramic. However, some soluble beryllium compounds, e.g. beryllium fluoride, may cause conjunctivitis. As previously stated, soluble beryllium compounds are rarely found in industry and are not used in EEE. Like many materials, beryllium metal and composites, beryllium-containing alloys and beryllium oxide ceramic particles can cause physical damage if sharp or abrasive particles enter the eyes.

3.6. Skin effects

Beryllium is classified as an irritant to the skin and as a potential skin sensitizer. The current classification is based on reports of dermal reactions from handling early grades of beryllium in the 1940s and early 1950s. These dermal reactions were later shown to be due to the presence of beryllium fluoride residues remaining in the metal from the fluoride extraction process. Beryllium fluoride contamination is not present in modern grades of beryllium metal and has not been a concern since the mid 1950s.

A study by Curtis[34] in the 1950s concluded that neither irritant skin effects nor sensitization occurred with any of the insoluble forms of beryllium materials or compounds, including beryllium metal. In 1996 a French animal study[35] found no skin reactions using a patch test to apply metallic beryllium to non-presensitized guinea pigs. The same study induced a moderate skin reaction in about half the animals only after repeated low level intra-dermal injections of a soluble beryllium sulphate solution.

Copper beryllium alloys and beryllium oxide ceramic are classified as potential skin sensitizers under the conventional method of classification, based on similar classification of beryllium itself. However, as beryllium was inappropriately classified as a skin sensitizer, so to are beryllium-containing alloys and beryllium oxide ceramics.

After several decades during which hundreds of thousands of tons of the beryllium-containing materials have been handled without special skin protection in hundreds of open workshops in all industrialized countries there is, in fact, no evidence that copper beryllium has skin-sensitizing properties. This element of the current classification should be disregarded for purposes of risk appraisal.

4. ENVIRONMENTAL ASPECTS OF BERYLLIUM IN EEE

4.1. Classification

Following review of the United States Environmental Protection Agency AQUIRE (AQUatic toxicity Information REtrieval) database for the toxicity levels of beryllium ion for aquatic organisms, and comparison of these levels with the results of transformation (‘solubility’) testing, the EU has assigned ‘no classification’ to beryllium metal, on the basis that it does not release toxic levels of Be ion under the most severe conditions of the transformation test, including the use of very fine beryllium powder and high water acidity.

U.S. EPA field studies in the Great Lakes water system found biota to be unaffected by low level emissions of beryllium solutions. It was also reported by the EPA that beryllium is not bioaccumulative.

4.2. Mining and extraction

The Western world receives the majority of its industrial beryllium requirements from one relatively small mining operation located in the semi-desert region of the Topaz-Spor Mountain area in the State of Utah, in the U.S.A. There are no beryllium mining operations in the EU. Other commercial mining operations are in the Republic of Kazakhstan and the Peoples Republic of China.

The ore mined in Utah is bertrandite, a hydrous beryllium silicate; $Be_4Si_2O_7(OH)_2$. Open pit mining is used. The ore body, which is visibly indistinguishable from surrounding materials, is located using precision sampling and GPS location techniques, followed by three-dimensional computer mapping. The topsoil and overburden are then stripped back to within centimetres of the ore body, and reserved. Once the ore is mined, land restoration is completed in accordance with U.S. mining regulations. The overburden is used to refill the pit and the topsoil is replaced and augmented as necessary. The area is then re-seeded with local plants. Considerable trials were made over several years to optimise these procedures, as measured by species monitoring for the return of native plant and animal life. These programmes, which are ongoing, have demonstrated that the land can be returned to its former state following bertrandite mining.

The bertrandite mined in Utah is chemically processed locally to beryllium hydroxide, enhancing the beryllium content by about 75 times. This hydroxide is then shipped to only two other facilities in the world where it can be further processed to the main products of the beryllium industry, i.e. beryllium metal and composites, beryllium-containing alloys and beryllium oxide ceramics.

4.3 Waste Management

The presence of beryllium or beryllium oxide in wastes, processing scrap or electronic scrap does not trigger hazardous waste management requirements. Beryllium is not a hazardous waste constituent nor is beryllium, in massive form, a listed hazardous waste under any Member State rules and regulations. A recent report on a study of the hazardous waste classification of discarded electrical and electronic equipment based on the potential to release toxic materials under RCRA (Resource Conservation and Recovery Act), did not report beryllium as a material of concern[36]. The hazardous waste constituents evaluated in this study were arsenic, barium, cadmium, chromium, lead, mercury, selenium and silver.

Beryllium and beryllium oxide do not present an environmental hazard when discarded in a landfill. Therefore, inclusion of beryllium or beryllium oxide in any directive to prevent electronic products from being improperly disposed of or discarded in landfills is not relevant. As noted by the Agency for Toxic Substances and Disease Registry (ATSDR) in its 2002 report[37], beryllium in soils, like aluminum, is very immobile because of its tendency to adsorb onto clay surfaces. Thus, beryllium has not been found to migrate or leach through soils to contaminate groundwater.

As beryllium is not classified as harmful to the environment, therefore its alloys are similarly unclassified, so far as its beryllium content is concerned. Even if beryllium were classified as toxic to the environment, copper beryllium alloys would remain unclassified under the rules for environmental classification because its typical beryllium content (2% maximum) is below the threshold level which triggers classification.

In any case, the alloys are supplied and used in massive form and are stable and inert under the range of conditions found in the natural environment.

It might be noted here that, should the alloys subsequently become classified for environmental hazards because of their copper or nickel content, then similar classification would apply to any potential replacement alloys which could be used for the manufacture of high performance electrical connection components, since they are all based on copper or nickel.

5. RECYCLING

As previously stated, the potential risk from the manufacture of beryllium-containing components is closely regulated, controlled and is confined to relatively few producers. The applications in which these components are used do not give rise to health or environmental risks. However, it is necessary to ensure safe disposal of beryllium-containing components at end-of-life, as well as safe recycle or disposal of scrap metal arising from its manufacture. Crushing, grinding or melting of beryllium-containing materials can cause an inhalation risk, and must be controlled under existing workplace regulations.

Like most metals, beryllium and beryllium oxide ceramic are eminently recyclable, and clean scrap can be sold back to the industry for direct recycling into new beryllium-containing products. The applications of beryllium metal and beryllium oxide ceramics, however, are highly specialized, and highly technological, rather than commercial or consumer in nature. As a result, many components have extremely long useful lives, and therefore return to the recycle stream very slowly. Some, because of their application in space, or because of their sensitive military nature, do not return at all.

Where EEE containing beryllium metal or and beryllium oxide ceramic components is to be recycled, it is recommended to extract them for direct recycling wherever possible. It is unusual for metallic beryllium and beryllium oxide ceramic to directly enter the normal metals recycling stream, mostly because of its monetary value as a clean scrap metal. However, should there be cases where such extraction is not viable, then judgement has to be used as to how to dispose of the EEE. If the EEE is to go through the normal recycling procedures of crushing, granulation, materials separation and melting of the metallic fractions, then, under existing workplace regulations, consideration needs to be given to potential health risk that could arise from the presence of beryllium at each of these stages. Ventilation and filtration systems may be necessary to control such risk, as required by existing regulations.

Copper beryllium alloys are fully recyclable materials. Clean scrap generated from alloy manufacture, i.e. off-cuts from rolling, extrusion and so on, and scrap generated from warehousing activities, plus component manufacturing scrap repurchased from customers, can go back directly into the manufacture of new alloy.

Most copper beryllium, however, reaches end-of-life as components in scrap equipment. Wherever the amount of copper beryllium in the equipment, and its accessibility, make it economically viable to extract and segregate the components for direct recycling, then this is the preferred route. In the vast majority of cases, however, the amount of copper beryllium in the equipment is very low, comprising just a few small components distributed throughout the equipment, and visually indistinguishable from other copper-based components.

Under these circumstances, it has not been practical or economic to identify, remove and segregate the copper beryllium components. Historically, they have remained in the equipment as it has gone through normal recycling procedures, to emerge as part of the general copper-based recycle stream. Both global estimates, based on the amounts of copper beryllium going into this stream, relative to the amounts of other copper-based materials, and actual tests of the copper recycle stream, have shown that the resulting beryllium levels in the recovered copper stream are below a level of concern.

In an effort to quantify the potential for worker exposure to airborne beryllium, a quantitative airborne metal exposure survey that was conducted in 2006 on workers shredding, roasting, milling, and assaying cellular phones at a recycling facility in the U.S.[38] (see attached) Cellular phones were used in this study because of the relatively high concentration of beryllium compared with other EEE. Based on the results of this study, beryllium exposures during shredding, roasting, milling and alloying operations of cellular phones using the work practice and ventilation controls described in this study, represent no inhalation hazard to the operators under existing workplace regulations.

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It has been alleged that there are health concerns regarding the recycling of materials and products containing beryllium. These reports of beryllium-related health issues in the recycling industry do not relate to the recycling and reclamation of alloy scrap or post-consumer electrical and electronic equipment but are attributable to an event several years ago resulting from the mishandling of metal drosses[39] by Noranda, a North American recycling company[40] (see attached). That metal dross came from a Brush Wellman's primary production facility. As a result, Noranda set a self-imposed, admittedly arbitrary limit of 200 ppm beryllium on all incoming recyclable, metal bearing materials including scrap metals, by-products, process scrap, electronic scrap, and post-consumer recyclables. Though Noranda admits its self-imposed limit has no health basis, it has encouraged others in the recycle industry to adopt similar limits. We are unaware of any reports of health impacts within the EU posed by the recycling of copper-beryllium alloy scrap and post-consumer recyclables. It is our understanding that the recycling operations within the EU utilize state of the art controls and practices such that any risk is adequately controlled.

6. SUBSTITUTION

Other metals, alloys and ceramics cannot be used as direct substitutes for beryllium, copper beryllium and beryllium oxide ceramic because no other materials offer the exact combination of properties required in high reliability, high performance EEE applications. Substitution only occurs when these high performance properties are not needed such as low-end disposable cellular phones.

In 2005, a project was conducted by the High Density Packaging User Group (HDPUG)[41] to identify and evaluate the performance, cost, availability and environmental attributes of potential substitutes for PVC cables, mercury-based lamps and beryllium-containing materials. The project identifies potential substitutes for copper beryllium alloys and beryllium oxide ceramics. However, the study found that *"few of the identified alternatives provide the same level of performance to CuBe alloys."* The project report also stated *"alternatives to beryllium containing ceramics do not appear to be well developed and do not appear to provide equivalent performance at the same cost."*

When performance and reliability are important in EEE, then there is no substitute for beryllium, copper beryllium alloys or beryllium oxide ceramic.

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