Product Safety Assessment Report

Product name: Professional microwave oven for the European market

July 2011

Panasonic Corporation

1. Preface

According to Article 33 of the REACH Regulation (Duty to communicate information on substances in articles), when an article contains a substance of very high concern (SVHC) stipulated in Article 59(1) of the same Regulation in a concentration exceeding 0.1 wt%, the supplier of said article is required to provide the recipient of the article with sufficient information to allow safe use of the article.

The two substances below listed in the SVHC List (Candidate List) released in January 13, 2010 are used in one of our professional microwave ovens as an insulator:

- Aluminosilicate Refractory Ceramic Fibres and
- Zirconia Aluminosilicate Refractory Ceramic Fibres. (as indicated in the original text)

Accordingly, assessment on the hazardousness of the substances and safety in use of the covered product containing these substances was conducted.

2. Basic information on the article

2.1 Product name

Professional microwave oven (for the European market; NE-C1475EUG/ NE-C1275BPQ)

2.2 Name of the SVHC contained in the article and intended use

(1) Substance name: Refractory ceramic fiber (RCF)

(2) Intended use: Insulator for microwave oven

3. Information on the SVHC in the article

Substance name	Refractory ceramic fiber (RCF)
CAS Number	(142844-00-6*)
EC Number	(650-017-00-8**)
Classification	Carc.1B H350i (according to the CLP Regulation)[1] Carc. Cat.2;R49 (according to Regulation 67/548/EEC)[2]
Concentration in the containing part of the article	50 wt% (the remaining 50% is E glass fiber)
Information on safe use	Wash the hands well after handling. Avoid contact with skin. Avoid contact with eyes. Do not inhale the dust[3].

* Reference CAS No. (copied from MSDS)

** index number

4. Detailed information on the SVHC

4.1 Identity of the substance

(1) Substance name: Refractory ceramic fiber

(2) Synonyms: Amorphous alumina-silica fiber
Ceramic fiber
Aluminosilicate

(3) CAS Number: 142844-00-6 (Reference)

(4) Molecular weight: Unidentifiable

(5) Chemical composition[4]: Al_2O_3: 43.5 - 47 % w/w, SiO_2: 49.5 - 53.5 % w/w
or
Al_2O_3: 45.5 - 50.5 % w/w, SiO_2: 48.5 - 54 % w/w

4.2 Physico-chemical properties

(1) Mean fiber length: 20-250 mm (Reference)

(2) Mean fiber diameter: 3 μm

(3) Maximum allowable use temperature: 1,260 °C

(4) Melting point: 1,760 °C

(5) Water solubility: Insoluble in water and organic solvents

(6) Other: Stable in air

4.3 Information on hazardousness

(1) Carcinogenicity assessment by international organizations etc.

Organization		Classification	Description	
ACGIH	(American Conference of Industrial Hygienists)	A2	Suspected human carcinogen	2001[5]
IARC	(International Agency for Research on Cancer)	2B	Possibly carcinogenic to humans	2002[6]
NTP	(National Toxicology Program)	R	Reasonably anticipated to be human carcinogens	2005[7]
U.S.EPA	(U.S. Environmental Protection Agency)	B2	Data in humans exist but are considered inadequate alone; data from animal studies are sufficient to indicate a carcinogenic potential in humans	1993[8]
EU	(European Commission)	Category 1B	May cause cancer by inhalation	2008[1]

(2) Specific examples in animal studies

In carcinogenicity tests with animals, the test results vary according to the laboratory animal type and the size/amount of administration/administration method of the fiber. Therefore multiple testing is required in order to determine the presence or absence of carcinogenic property.

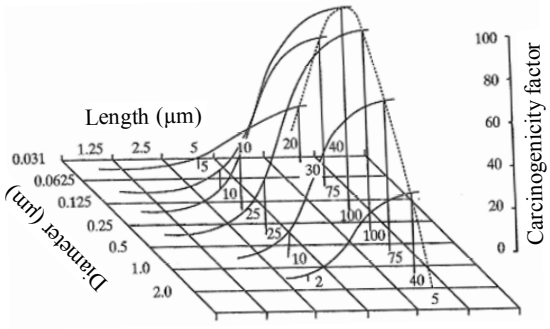
Inhalation of RCF in rats has been reported to cause pulmonary fibrosis and increase in the incidence of lung cancer[5]. In a 2-year inhalation study for rats[9], the rats were exposed to heat-treated RCFs having a 1 μm diameter and 20 μm length for 6 hours/day, 5 days/week for 24 months at an inhalation concentration of 30 mg/m^3 (approx. 220 fibers/cc). Four types of RCFs including an RCF with kaolin as raw material were used.

(3) Information on environmental impact

There is no data regarding ecological impact.

5. Risk assessment for human health

Due to the nature of asbestos being a fibrous substance, the carcinogenicity issues of other fibrous substances besides asbestos have gained attention. The awareness of fiber size relating to carcinogenicity grew with the global spread of the Stanton-Pott hypothesis shown in the figure below, namely, the hypothesis that carcinogenicity is not limited to asbestos but generally found in thin, long fibers and that those with a fiber diameter of 0.25 μm and a length of 20 μm have the most carcinogenicity[10].



The ceramic fiber used as an insulator in the present product (professional microwave oven) is classified under Group 2B, "Possibly carcinogenic to humans," by IARC, and its hazardousness is the basis for being listed in the Candidate List of substances of very high concern (SVHC) under the EU REACH Regulation. Additionally, other organizations also classify the substance as having concerns of carcinogenicity or as a substance with suspected carcinogenicity (see 4.3(1) Carcinogenicity assessment by international organizations etc.)

The ILO (International Labour Organization)[11] defines inhalant fibers as "fibers wherein the diameter is 3 μm or less, length is 5 μm or more (by measurement), and the aspect ratio (length/diameter) is 3 or more." Since the ceramic fiber used in the covered microwave oven has a mean diameter of 3 μm, which is within the scope of the aforementioned definition of inhalant fibers, it is necessary to conduct exposure assessment to ensure that the refractory ceramic fibers used in the product is not dispersed and that the user is not exposed to the substance.

5.1 During use of the product

The insulator used for assembling and manufacturing the microwave oven is supplied and used in a form of a mat sheet made of ceramic fiber and glass fiber blended together. The surface of the sheet is coated with resin to prevent the fibers from diffusing during handling.

In manufacturing the product, the sheet material is punched out into the shape of the product and carefully inserted inside the equipment for assembly. As a result, the insulator is fixed in the space between the cooking chamber of the microwave oven and the insulating cover structured on the outside of the cooking chamber.

However, due to the following reasons, ceramic fiber may be diffused from the space set with the insulator, and further may be diffused outside through the air cooling path of the microwave oven:

- the resin coating to prevent the diffusion of fibers easily deteriorates with the high temperature when cooking is done in the oven, which causes the fibers to lose its fixing capability
- air may flow in/out of the space set with the insulator through operation and pause of the microwave oven, because (a) the part connecting the outer wall of the cooking chamber and the insulating cover has a slight space, and (b) tiny holes formed during the process are present on the insulating cover.

5.1.1 Exposure assessment using an actual product used in the market for two years

(1) Objective

Possibility of exposure caused by the use of the microwave oven was assessed by disassembling a covered microwave oven used in the market for two years and seeing whether ceramic fibers are diffused inside the cooking chamber and around the oven.

(2) Test method and analysis method

A subject microwave oven used in the market for two years was disassembled, and a lump containing fibrous substances adhered near the insulator-storage inside the oven was scraped off and collected. The sample was washed with acetone, fixed onto double-faced conductive tape and coated with carbon for form observation (diameter and length) and qualitative elemental analysis (covered elements: $_{11}$Na - $_{92}$U) using SEM (scanning electron microscope) and EDX (energy-dispersive X-ray spectroscopy).

For comparison, analysis on the form (diameter and length) and chemical composition was similarly performed with SEM and EDX for the same type of insulator in the subject product but this time at an unused state.

(3) Test results

The results of the SEM observation and EDX qualitative elemental analysis indicate that all of the fibrous substances collected were about 8 to 10 μm in diameter, and were fibers with the compositions of: Al_2O_3: 17-18%; SiO_2: 52-54%; and CaO: 27-28%. The fibers were found to be identical to E glass fibers, which account for 50% of the substances contained in the product used for comparison.

5.1.2 Exposure assessment using a new microwave oven

(1) Objective

Assuming that fibrous substances used in the insulator adhere to the inside of the microwave oven during the assembly process, there may be cases where the fibrous substances diffuse out from inside of the oven. Exposure assessment for human health was conducted.

(2) Test method and analysis method

Air from the spot where air is emitted from inside of the oven was collected in a filter at 10 L/min for 60 min. 50 graticules were subject to secondary electron image observation with SEM to count the number of fibrous substances. In addition, EDX qualitative elemental analysis was performed on the observed fibrous substances. As a blank sample, the air inside the laboratory was similarly collected and analyzed. Fiber concentration was calculated from the results of counting for assessment.

(3) Test results

The collected fibers from neither the blank or air inside the oven indicated the same composition as ceramic fiber. Fibers consisting primarily of Al_2O_3: 3-4% and SiO_2: 63-65% were observed. (1 in blank; 12 inside the oven)

Fiber concentration (amount of exposure) was calculated with the following equation:

$$C_F = \frac{(AN - A_b N_b)}{a \times n \times Q \times 10^3}$$

C_F : Fiber concentration (Amount of Exposure)
A : Effective collection area of the filter (mm^2)
A_b : Effective area of the filter for blank measurement (mm^2)
a : Graticule area (mm^2)
N : Total fiber count for the sample (f)
N_b : Average number of fibers on the blank filter (f)
n : Number of fields observed for the sample (-)
Q : Amount of air suction (L)

5.1.3 Exposure assessment after accelerated aging with an actual product using a new microwave oven

(1) Objective

The insulator of the subject product is treated with anti-diffusion on the surface to prevent exposure to workers handling fibers and to ensure workability. However, it has been found that the anti-diffusion agent gradually burns away in the course of using the microwave oven at a high temperature (such as the grill function) and the fixing capability of the fibers are eventually lost.

In addition, although the insulator is stored in a compartment set in a manner surrounding the cooking chamber, it is not airtight. Therefore it can be anticipated that the insulator storage will have entry/exit of the surrounding air according to the rising or drop of temperature due to the ON/OFF state (including the ON/OFF state of the grill heater) of the microwave oven. RCF may leak out depending on the airflow during this time.

Accordingly, exposure assessment was conducted to identify the risks of emission/diffusion of fibrous substances outside the oven after the anti-diffusion agent has burned away with prolonged operation.

(2) Test method and analysis method

The microwave oven was operated for 1,000 hours to conduct an accelerated aging test (Condition: Repeat the cycle of 20 min in ON and 5 min in OFF at GRILL). The fan was run after operating the product in the above condition for 1,000 hours, and air was collected in a filter at 10 L/min for 60 min from the spot where air is emitted from inside of the oven. Additionally, as a blank example, air was collected under the same suction condition at a point approx. 2 m away from the equipment subject to measurement. Observation and analysis of the fibrous substances were conducted in the same manner as in 5.1.2(2).

(3) Test results

The collected fibers from neither the blank or air inside the oven indicated the same composition as ceramic fiber. Fibers with the composition of Al_2O_3: 3-4% and SiO_2: 63-65% were observed (15 in blank; 6 inside the oven). Fibers were identical to the fibrous substances observed in the initial operation measurement. More fibers were observed in the blank.

5.1.4 Identification of the fibrous substances observed

The results showed that ceramic fiber does NOT diffuse. However, in order to identify the fibrous substance with unknown generation source observed in the tests of 5.1.2 and 5.1.3, fibrous substances that are likely to be airborne around the laboratory were tested for analysis.

(1) Fibers analyzed

(i) SGM10-100

Insulator where in over 98% of the composition is glass fiber, and used in products for the Japanese market. Supply is limited to a single supplier.

(ii) VIP (Vacuum Insulation Panel)

Insulator where glass fibers (silica-base) are enclosed and the inside is vacuumized. Production line was present near the laboratory.

(2) Analysis method

Observation and qualitative elemental analysis (covered elements: $_{11}$Na - $_{92}$U) was performed on the form (diameter and length) using SEM and EDX.

(3) Analysis results

(i) SGM10-100

Fibers with the composition of Al_2O_3: 17-18%, SiO_2: 52-54%, CaO: 27-28% were observed. Fiber diameters were 8-9 μm, which were different from the composition or form of the fibrous substance observed.

(ii) VIP (Vacuum Insulation Panel)

Fibers with the composition of Al_2O_3: 3-4%, SiO_2: 63-65% were observed. Fiber diameters varied from 0.68 μm to 1.8 μm. Because the chemical composition and form were identical to the fibrous substance with unknown generation source observed in the tests of 5.1.2 and 5.1.3, this unknown fiber was identified as VIP.

5.1.5 Risk characterization

ACGIH advises permissible concentration in working environments, and sets refractory ceramic fibers (RCFs) to 0.2 f/cm^3 - TWA[12]. Since TWA is defined as "time-weighted average concentration to which most adults in good health may be repeatedly exposed without adverse effect 8 hours a day, 40 hours a week," it can be assumed as a no-observed-adverse-effect level to healthy human adults. Therefore, according to the appendix to "Technical Guidance for Risk Assessment regarding Priority Assessment Chemical Substances under the Chemical Substances Control Law" released by the National Institute of Technology and Evaluation (NITE)[13], the relation between NOAEL and TWA to healthy human adults can be estimated as in the equation below:

NOAEL to a healthy human adult [f/m^3]

$$= \text{TWA [f/m}^3\text{]} \times 8/24 \times 5/7 \times 1/a = \text{TWA [f/m}^3\text{]} \times 1/10 \qquad \text{--- (Equation 1)}$$

Note that (8/24 × 5/7) is for time correction, and 1/a is the difference between the working environment uncorrectable with simple conversion of exposure time and the general environment. Specifically, this is a correction factor taking into account that recovery may be possible with intermittent exposure in working environment only but there is no recovery period with continuous exposure in general environment. 1/10 is used here as a total in time correction.

In addition, in the hazardous assessment to humans under REACH, it is necessary to calculate DNEL (Derived No-Effect Level) for each exposure path attributable to a specified use[14]. DNEL is obtained by dividing NOAEL by the assessment factor (AF). Note that assessment factor (AF) is a correction factor set by (a) uncertainty caused by variations in experiment data, variances within species, and variances with other species, (b) property and degree of impact, and (c) uncertainty due to the variance in exposure frequency and concentration. In this assessment, the number of uncertainty attributable to variances within species at (a) should be considered. Accordingly, the following equation is made with the conversion using AF=10:

$$\text{NOAEL to a healthy human adult [f/m}^3\text{]/AF} = \text{TWA [f/m}^3\text{]} \times 1/100 \qquad \text{--- (Equation 2)}$$

As for exposure factor, the $DNEL_{RCF}$ can be calculated as below, using the standard value according to a handbook issued by the U.S. Environmental Agency (EPA)[15], where the inhalation rate of adult males weighing 70 kg is 21.4 m^3/day in moderate activity levels.

$$DNEL_{RCF} = 0.2\ [\text{f/cm}^3] \times 10^6\ [\text{cm}^3\text{/m3}] \times 21.4\ [\text{m}^3\text{/day}] \times 1/70\ [\text{kg}] \times 1/100$$
$$= 611\ [\text{f/kg/day}] \qquad \text{--- (Equation 3)}$$

From this, the results are indicated by the risk characterization ratios (RCRs) used for determining whether risks are properly controlled. Whether or not risks are properly controlled is evaluated with RCR value, and indicated in the following equation:

$$\text{RCR} = \frac{\text{Amount of exposure}}{\text{DNEL}} \qquad \text{--- (Equation 4)}$$

Evaluation would be:
when RCR is less than 1, namely, when the amount of exposure is less than DNEL, risks are properly controlled; or
when RCR is greater than 1, namely, when the amount of exposure is greater than DNEL, risks are not properly controlled.

Although ceramic fibers were not detected in the exposure test for refractory ceramic fiber, evaluation is to be conducted as Amount of exposure = Quantitative lower limit.

Since the quantitative lower limit (S) with an upper limit of 95% confidence limit can be calculated by the equation below, the figure can be obtained by assigning the values as the following. As the total number of fibers (N) for analysis, 2.645 is used, where the 95% upper limit is added to the assumption of detection of one fiber to be on the safe side:

$$S = \frac{2.645 \times A}{a \times n \times Q \times 10^3} = 9.37 \times 10^{-5}\ [\text{f/cm}^3]$$

When the measurement condition of 10 L/min × 60 min (=14.4 m^3/day) is converted into the inhalation rate in moderate activity levels, 21.4 m^3/day, the value would be as follows:

$$9.37 \times 10^{-5}\ [\text{f/cm}^3] \times 14.4/21.4 = 6.305 \times 10^{-5}\ [\text{f/cm}^3]$$

Further, the amount of exposure can be obtained by the following calculation, using the inhalation rate of 21.4 m^3/day in moderate activity levels of adult males weighing 70 kg, the use environment of the actual professional microwave oven (12 hours a day, 5 days a week), and DNEL_{RCF} calculation:

$$\begin{aligned}\text{Amount of exposure (RCF)} &= 6.305 \times 10^{-5}\ [\text{f/cm}^3] \times 10^6\ [\text{cm}^3/\text{m}^3] \times 12/24 \times 5/7 \times 21.4\ [\text{m}^3/\text{day}] \times 1/70\ [\text{kg}] \\ &= 6.884 \approx 6.9\ [\text{f/kg/day}]\end{aligned}$$

Therefore, RCR would be indicated as the equation below:

$$\text{RCR} = \frac{\text{Amount of exposure (RCF)}}{\text{DNEL}_{\text{RCF}}} = \frac{6.9\ [\text{f/kg/day}]}{611\ [\text{f/kg/day}]} = 0.011$$

Consequently, RCR < 1 implies that the risks regarding exposure to RCF are small enough.

[Reference 1]

In the exposure test during product use, specifically in "Exposure assessment using a new microwave oven" of 5.1.2, the numbers of fibers observed were: 1 in the blank and 12 inside the oven. This test turned out to have the most exposure among all of the present exposure tests.

Although all of the fibrous substances observed had different compositions as ceramic fibers (see VIP: 5.1.4 (3) (ii)), if these fibrous substances were to be tested for exposure assessment, the amount of exposure can be calculated with the following equation:

$$C_F = \frac{(AN - A_b N_b)}{a \times n \times Q \times 10^3}$$

C_F : Fiber concentration (Amount of Exposure)
A : Effective collection area of the filter (mm^2)
A_b : Effective area of the filter for blank measurement (mm^2)
a : Graticule area (mm^2)
N : Total fiber count for the sample (f)
N_b : Average number of fibers on the blank filter (f)
n : Number of fields observed for the sample (-)
Q : Amount of air suction (L)

$$C_F\,(\text{VIP}) = 0.000268 \quad [\text{f/cm}^3]$$

Therefore, the amount of exposure of VIP calculated using the use environment of the actual professional microwave oven (12 hours a day, 5 days a week) and the inhalation rate of 21.4 m^3/day in moderate activity levels of adult males weighing 70 kg would be as below:

Amount of VIP exposure:

Amount of exposure (VIP) = 0.000268 [f/cm^3] × 10^6 [cm^3/m^3] × 12/24 ×5/7× 21.4 [m^3/day] × 1/70 [kg]
= 29.3 [f/kg/day]

$$\text{RCR} = \frac{\text{Amount of exposure (VIP)}}{\text{DNEL}_{\text{RCF}}} = \frac{29.3\,[\text{f/kg/day}]}{611\,[\text{f/kg/day}]} = 0.048$$

Accordingly, assuming that even if the detected fibers were RCR, risks are properly controlled since the calculation result indicates RCR < 1.

[Reference 2] Existing standards for control

Control concentration:	
Inhalant dust: 3.0 mg/m^3 $E = \frac{3.0}{1.19Q + 1}$ (E: Control concentration mg/m^3, Q: Free silic acid content rate)	Working Environment Evaluation Standards, Ministry of Labor Notification No. 79[16]
Permissive concentration (Exposure threshold, biological exposure index)	
Inhalant dust: 1 mg/m^3, total dust: 4 mg/m^3	Japan Society for Occupational Health (2007)
0.2 f/cm^3 - TWA (Fibers that are: 5 μm or longer, less than 3 μm in diameter, and 3 or more in aspect ratio (length/diameter))	ACGIH (2007)[12]

* TWA: Time-weighted average; 8 hours

5.2 Product disposal

As described in 5.1, when the microwave oven is used for oven cooking where the temperature becomes high, the fixing capability of ceramic fiber is lost due to deterioration of the resin coating of the insulation sheet. Therefore, because it can be anticipated that collective shredding treatment at the time of product disposal may cause diffusion of refractory ceramic fibers, a relatively extensive exposure control during the process of product disposal is required.

Under the EU WEEE Directive (Directive on treatment of waste electric and electronic equipment), selective treatment is required for parts containing substances with concerns of hazardousness in disposal (Article 6), and the substances to which the requirement shall apply are specified in ANNEX II. Refractory ceramic fibers are listed in ANNEX II, and information is provided to treatment facilities (Article 11). The treatment facilities then handle the hazardousness in product disposal processes by selective treatment for covered parts, in accordance with the information provided.

Thus, risks to the health during product disposal are handled at product treatment facilities.

6. Conclusion

Risks to the health of workers who use professional microwave ovens with an insulator containing ceramic fibers were evaluated with RCR (Risk Characterization Ratios), and it was confirmed that measures in response to the EU WEEE (selective treatment) are required at the time of disposal.

Risks are determined to be properly controlled when RCR is below 1 in RCR risk assessment. In the present article, specifically a microwave oven using refractory ceramic fibers as an insulator, diffusion of refractory ceramic fibers was not detected from the main body during use, which has low possibility of exposure during product use. Additionally, because measures such as that described above are required under the EU WEEE Directive at the time of product disposal, it can be concluded that RCR is below 1, which also means that the health risks during use of the microwave oven is low.

References

[1] Regulation (EC) No 1272/2008 (CLP) Annex VI, Part 3, Table 3.1

http://echa.europa.eu/legislation/classification_legislation_en.asp

(See "Harmonised classification and labelling for certain hazardous substances." Annex VI, Table 3.1 (MS Word, 10 MB))

[2] Regulation (EC) No 1272/2008 (CLP) Annex VI, Part 3, Table 3.2

http://echa.europa.eu/legislation/classification_legislation_en.asp

(See "Harmonised classification and labelling for certain hazardous substances." Annex VI, Table 3.2 (MS Word, 9 MB))

[3] Japan Advanced Information Center of Safety and Health; GHS model; MSDS information

http://anzeninfo.mhlw.go.jp/anzen/gmsds/cas-142844-00-6.html

[4] ECHA Candidate List of Substances of Very High Concern for authorisation

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

[5] ACGIH(2001) Synthetic Vitreous Fibers

[6] IARC monograph summary, Volume 81 (2002)

http://monographs.iarc.fr/ENG/Monographs/vol81/mono81.pdf

[7] NTP 11th(2005) Ceramic Fibers (Respirable Size)

[8] EPA (1993) Refractory ceramic fibers II.A.1. Weight-of-Evidence Characterization

http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showQuickView&substance_nmbr=0647

[9] Inhalation Toxicology, 7:425-467, 1995 (Mast)

[10] Fibrous Substance Measurement Manual, Japan Association for Working Environment Measurement

[11] ILO (International Labour Organization); Asbestos Convention, 1986 (No. 162)

[12] ACGIH (2007) TLVs

[13] Technical Guidance for Risk Assessment regarding Priority Assessment Chemical Substances under the Chemical Substances Control Law, Appendix

http://www.safe.nite.go.jp/risk/pdf/21fy_tech_guidance_huzoku.pdf

[14] Guidance on information requirements and chemical safety assessment Chapter R.8
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=16_12_10

[15] Exposure Factors Handbook :2009 Update (EPA/600/R-09/052a) Chap.6 Inhalation Rates

http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=492239

[16] Working Environment Evaluation Standards, Ministry of Labor Notification No. 79

http://www.jniosh.go.jp/icpro/jicosh-old/japanese/country/japan/laws/02_enf/2_criterion_std/index.html