EVEREST CONSULTING ASSOCIATES INC.
15 N. MAIN STREET, CRANBURY, NJ 08512, USA
(609) 655-7426 — (609) 655-5637 (FAX)

E-Mailed Memo

Date: October 20, 2015 (updated)[1]

To: Dr. Dean Venturin, Unifrax

From: L. Daniel Maxim and Ron Niebo, Everest Consulting Associates

Subject: GHS Classification of RCF

Introduction

As the Global Harmonization System is now beginning to be implemented in the United States, you asked *Everest Consulting Associates* (ECA) to offer an opinion on the appropriate GHS carcinogen classification for *refractory ceramic fiber* (RCF).[2]

Recommendation

Our conclusion regarding proper classification is identical to that reached in 2006. There is no basis for placing RCF in Category 1A (known to have carcinogenic potential for humans) because the available epidemiological evidence, though limited, indicates that the members of the occupationally exposed cohort show no evidence of interstitial fibrosis, elevated lung cancer rates (compared to baseline rates), and no cases of mesothelioma. Thus, the logically possible choices for self-classification are reduced to Category 1B (presumed to have a carcinogenic potential for humans) and Category 2 (suspected human carcinogen).

Selection of the most appropriate GHS category (between the categories 1B and 2) is ultimately a matter of judgment. In our judgment, it is appropriate to place RCF in Category 2. We are mindful that the IARC working group concluded on a weight of evidence basis, that the animal evidence provided sufficient, rather than limited evidence

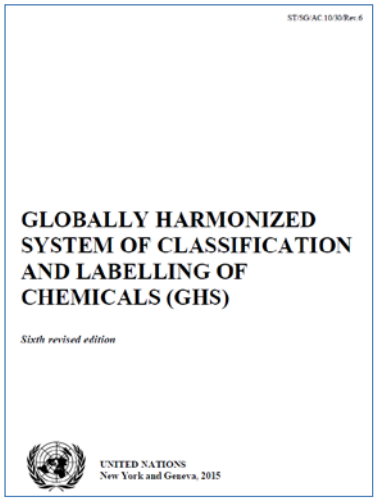
[1] This memo is updated from the initial March 24, 2014 version.

[2] We considered this issue before and wrote a memorandum summarizing our recommendation with supporting detail on 24 May 2006.

of carcinogenicity. However, this group also acknowledged that there was room for doubt. There is certainly abundant evidence that lung overload can lead to inflammation and tumors in laboratory inhalation studies of rodents. Moreover, the applicable OSHA guidance document (Appendix F within the OSHA document) indicates that, even if RCF falls into IARC Group 2B, the correct match is to GHS Category 2.

Background

In 2003, the *United Nations* (UN) adopted the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The GHS is a system for standardizing and harmonizing the classification and labelling of chemicals. It is a logical and comprehensive approach to:


ST/SG/AC.10/30/Rev.6

GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Sixth revised edition

UNITED NATIONS
New York and Geneva, 2015

- Defining health, physical and environmental hazards of chemicals;
- Creating classification processes that use available data on chemicals for comparison with the defined hazard criteria; and
- Communicating hazard information, as well as protective measures, on labels and *Safety Data Sheets* (SDS).

Among other things, the GHS includes criteria for the classification of health, physical and environmental hazards, as well as specifying what information should be included on labels of hazardous chemicals as well as safety data sheets. Over time the relevant UN guidance document has been revised and is now in its sixth edition (2015).[3]

Figure 3.6.1: Hazard categories for carcinogens

CATEGORY 1:	**Known or presumed human carcinogens**
	The placing of a substance in Category 1 is done on the basis of epidemiological and/or animal data. An individual substance may be further distinguished:
Category 1A:	**Known to have carcinogenic potential for humans; the placing of a substance is largely based on human evidence.**
Category 1B:	**Presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence.**
	Based on strength of evidence together with additional considerations, such evidence may be derived from human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen). Alternatively, evidence may be derived from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.
	Classification: Category 1 (A and B) Carcinogen
CATEGORY 2:	**Suspected human carcinogens**
	The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1. Based on strength of evidence together with additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.
	Classification: Category 2 Carcinogen

[3] Available electronically at http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev06/English/ST-SG-AC10-30-Rev6e.pdf.

The GHS hazard categories[4] for carcinogens are shown in Figure 3.6.1 of the latest UN GHS guidance document (reproduced below). These include:

- Category 1 (known or presumed human carcinogens), further subdivided into Category 1A (known to have carcinogenic potential for humans) and Category 1B (presumed to have a carcinogenic potential for humans), and
- Category 2 (suspected human carcinogen).

These three (1A, 1B, and 2) are the applicable carcinogen classification Categories to be used under GHS. According to the UN document and proposed OSHA regulations this classification is based on the *weight and strength of evidence* from available (human and animal data). The UN documentation (3.6) provides additional useful guidance for classification including (3.6.2.5) "some important factors which may be taken into consideration when assessing the overall level of concern…"

The UN GHS guidance document references and contains excerpts from the classification criteria used by the *International Agency for Research on Cancer* (IARC). Although the IARC carcinogen classification scheme differs from that used by GHS—for example, IARC partitions materials into five groups (1, 2A, 2B, 3, and 4) rather than three, there is a clear mapping between these two classification systems.

US Regulation

GHS is now being implemented in the United States (the Final Rule became effective May 26, 2012),[5] so it is necessary to address RCF and, more specifically, the appropriate carcinogen classification for this fiber. The *Occupational Safety and Health Administration* (OSHA) is the key federal agency in the US that addresses hazard communication, labeling, and related issues. OSHA originally published a proposed rulemaking on September 30, 2009 to align OSHA's *Hazard Communication standard* (HCS) with the GHS.[6] This OSHA rule (among other things) *requires chemical manufacturers or importers to classify the hazards of chemicals which they produce or import*, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, safety data sheets, and information and training. OSHA has developed various guidance documents to assist companies in implementing GHS including how to employ the self-classification system.[7] Among the OSHA guidance documents, Appendix A[8] addresses classification and specifically notes that

[4] GHS categories differ from those used by other agencies, such as IARC or NTP.
[5] See https://www.osha.gov/dsg/hazcom/HCSFactsheet.html for implementation dates for this rule.
[6] Proposed regulatory text available at https://www.osha.gov/dsg/hazcom/hcs_reg_text_093009.pdf.
[7] See e.g., https://www.osha.gov/dsg/hazcom/ghsguideoct05.pdf, https://www.osha.gov/dsg/hazcom/appendix_a.pdf, and https://www.osha.gov/dsg/hazcom/appendix_f.pdf.
[8] See https://www.osha.gov/dsg/hazcom/appendix_a.pdf.

(A.0.3 and A.6.2) that for carcinogen classification *it is necessary to consider both the strength and weight of evidence.* (Substantive comments relative to RCF carcinogen classification are covered in a separate section.)

-Classification based on other authoritative agency determinations

However, in lieu of directly applying the strength/weight criteria, OSHA offers another option for companies seeking to classify materials (see section (A.6.4)[9]):

> "A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:
> A.6.4.1.1 National Toxicology Program (NTP), "Report on Carcinogens" (latest edition);
> A.6.4.1.2 International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions)
> A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen."

To facilitate use of this (A.6.4) alternative, OSHA offers (in Appendix F[10] of their guidance documents) the following:

> "Part D. Table Relating Approximate Equivalences among IARC, NTP RoC, and GHS Carcinogenicity Classifications
>
> The following table may be used to perform hazard classifications for carcinogenicity under the HCS (§1910.1200). It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix."

The relevant portion of the table that addresses the correspondence between GHS and IARC Classification is reproduced in Table 1:

[9] See page 43 of https://www.osha.gov/dsg/hazcom/appendix_a.pdf.
[10] See https://www.osha.gov/dsg/hazcom/appendix_f.pdf.

TABLE 1. *Approximate equivalence among carcinogen classification schemes.*

IARC	GHS
Group 1	**Category 1A**
Group 2A	**Category 1B**
Group 2B	**Category 2**

In 1988 an IARC Working Group reviewed the available evidence for RCF and placed RCF in Group 2B (*possibly carcinogenic to humans*). This classification was reaffirmed by a subsequent Working Group meeting in 2001 (IARC, 2002). Although additional studies on RCF have been published since 2001, there is no study that would justify a revision in the IARC classification decision in favor of placing RCF in either Group 2A or Group 1. Thus, using the available OSHA guidance provided by para A.6.4.1.2, it would be appropriate to place RCF in Category 2 of the GHS. (We recognize that this classification decision differs from that made under REACH, a topic discussed in another section below.)

Criterion A.6.4.1.1 might also be used for guidance, and RCF is listed in the 13th Edition of the Report on Carcinogens as *reasonably anticipated to be human carcinogens* based on sufficient evidence of carcinogenicity from studies in experimental animals.[11] According to the above mentioned Appendix F, this NTP category does not have a unique correspondence to the GHS categories—instead it matches both GHS Category 1 B and 2, so it is not informative in this respect.

The Z-tables do not list RCF, so Criterion A.6.4.2 cannot be used to define a GHS classification.

-Classification based on strength and weight of evidence

As noted above, we originally examined this question in 2006. Since that time nothing has occurred to change our view. The balance of this section addresses RCF self-classification in the light of available experimental evidence.

-Feasible Category Choices

Based on the available data for RCF, which include both animal and human studies, Category 1A can be ruled out. There is no human evidence to suggest that RCF is carcinogenic—indeed (see below), although limited, the available epidemiological data suggest the opposite. Thus, logically possible category choices for RCF are either Category 1B or Category 2.

In making the choice between Category 1B and Category 2, the OSHA GHS guidance document notes that two (strength and weight of evidence) criteria are relevant:[12]

[11] See http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html and http://ntp.niehs.nih.gov/ntp/roc/content/13throc.zip.

[12] See page 40 of https://www.osha.gov/dsg/hazcom/appendix_a.pdf.

> "A.6.2.3 Carcinogen classification is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories."

This OSHA document addresses strength of evidence as follows:

> "A.6.2.4 Strength of evidence involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms "limited" and "sufficient" have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory Appendix F.)"

Ongoing morbidity (including the study of symptoms, pulmonary function testing, and chest x-rays) and mortality studies of various cohorts occupationally exposed to RCF (see Burge *et al.*, 1995; Cowie *et al.*, 2001; Greim *et al.*, 2014; LeMasters *et al.*, 1998, 2003; Lockey *et al.*, 1996, 1998, 2002, 2012; Maxim *et al.*, 2015; McKay *et al.*, 2011; Trethowan *et al.*, 1995; Utell and Maxim, 2010; Walker *et al.*, 2002, 2012 a, b) have failed to reveal any interstitial fibrosis, incremental lung cancer, or any cases of mesothelioma, so there is no basis for claiming that there is any evidence for carcinogenicity in humans.

The relevant animal data for classification are the so-called RCC inhalation bioassays on rats (Mast *et al*, 1995 a, b) and hamsters (McConnell, 1995), which indicated that rodents exposed to elevated concentrations of RCF developed fibrosis, lung cancer, and mesothelioma. The IARC working group (IARC, 2002) concluded that there was sufficient evidence for the carcinogenicity of RCF. (However, [see below] this group acknowledged that interpretation of these studies was not straightforward and, moreover, more has been written on the topic since the IARC meeting.)

The RCC studies were believed to the "state of the art" at the time. However, subsequent analysis of these studies concluded that overload was likely (Mast *et al*., 2000 a, b)—chiefly because of a high and non-representative amount of particles in the exposure aerosol (Maxim *et al*., 1997)—and that it was not possible to assess the relative contribution of these particles to the observed response (see e.g., Brown *et al*., 2005 and

contained references). The IARC working group acknowledged possible confounding (IARC, 2002 at p. 233);

> "The Working Group noted that the greater particulate fraction of RCF 1 could have influenced the development of inflammation and subsequent carcinogenic response in the chronic inhalation studies of RCF 1. The extent of this influence is difficult to assess quantitatively."

The interpretation of the limitations of the RCC studies on RCF is critical to the appropriate categorization of RCF.

ECFIA has petitioned the European Union to reclassify RCF for scientific reasons discussed at length in Brown *et al*. (2005). The essence of the argument for reclassification is that while the RCC animal experiments certainly resulted in fibrosis and tumors, these could have been caused by lung overload (itself an artifact of a non-representative ratio of particles to fibers) and, therefore, the animal studies are of limited utility for assessing carcinogenicity. If so, according to the OSHA GHS categorization guidance found in Appendix F:

"(ii) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the study."

I was one of the authors of the Brown et al. (2005) manuscript and I believe that there are legitimate concerns regarding the adequacy of the RCC evidence. Dr. Hartwig Muhle, one of the members of the IARC working group and frequent attendee at IARC meetings, was another author of the Brown et al. (2005) paper. This said, the EU has not reclassified RCF.

OSHA Appendix A indicates that additional factors may be relevant:

> "A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:"

And listed among these factors is:

> "(j) The possibility of a confounding effect of excessive toxicity at test doses;"

Item (j) in this list specifically includes the possibility of overload.

Based on both weight/strength arguments and the correspondence between IARC categories and GHS categories listed in OSHA's Appendix F, it is reasonable to self-classify RCF into Category 2.

-REACH

While self-classification of chemical substances is also employed in Europe, there is no option for RCF classification under REACH.[13] This is because under the previous labelling system used in Europe, the 1997 Dangerous Substances Directive, RCF was listed as a Category 2 carcinogen based only on animal studies. The Dangerous Substances Directive is being phased out in favor of the new globally harmonized system.

The phase-out process began with EC Regulation No. 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging (CLP) of substances and mixtures. This CLP regulation, as amended from time to time, is replacing step-by-step the older Dangerous Substances Directive. As part of the transition to the new CLP regulation, substance category labels under the Dangerous Substance Directive were 'translated' into the CLP globally harmonized system, a new but equivalent scheme for classification and labelling in 2009. *As a result the old Category 2 Carcinogens are now automatically classified as Category 1B carcinogens* which are substances "presumed to have carcinogenic potential for humans, classification is largely based on animal evidence."

Recommendation

Selection of the most appropriate GHS category (between the categories 1B and 2) is ultimately a matter of judgment. *In our judgment, it is appropriate to place RCF in Category 2*. We are mindful that the IARC working group concluded on a weight of evidence basis, that the animal evidence was sufficient, rather than limited. However, this group also acknowledged that there was room for doubt. There is certainly abundant evidence that lung overload can lead to inflammation and tumors in laboratory inhalation studies of rodents. Moreover the OSHA guidance document (Appendix F) indicates that, even if RCF falls into IARC Group 2B, the correct match in the GHS is to GHS Category 2. It is ironic that the GHS was designed to produce greater alignment among the regulatory schemes of various countries yet RCF would be placed in two different categories in the US and Europe. Nonetheless, we believe that it is logical to self-classify RCF in Category 2 given the available US guidance. It does not make sense to perpetuate an error by placing RCF in Category 1B simply to ensure consistency with the classification in Europe.

The self-classification decision in the US has obvious implications for Canada as well. On February 4, 2011, the Prime Minister of Canada and the President of the United States (U.S.) established the Canada-U.S. *Regulatory Cooperation Council* (RCC). The RCC is designed to align Canadian and American regulatory approaches in various sectors.

In December 2011, the Joint Action Plan for the Canada-U.S. RCC was announced. It includes a key commitment to "align and synchronize implementation of common classification and labelling requirements for workplace hazardous chemicals

[13] See e.g., http://echa.europa.eu/documents/10162/465d71a1-3510-4701-96a7-d347f63d0785.

within the mandate of the U.S. Occupational Safety and Health Administration (US-OSHA) and Health Canada."

Implementing the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for workplace chemicals in Canada and the U.S. will meet this commitment. The Canadian GHS website references the UN website for classification criteria (http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/preparing-preparation/suppliers_employers-fournisseurs_employeurs-eng.php).

-Closing comment

Whether difficult to interpret or not, the RCC studies certainly do not exonerate RCF. RCF is durable compared to many other *synthetic vitreous fibers* (SVFs)[14] and as produced and handled, some RCF is respirable. For these reasons it is important to maintain the product stewardship program for RCF and to continue to seek ways to minimize occupational exposure. Unifrax and other firms in the industry continue to monitor the scientific literature—indeed, these firms have sponsored most of the scientific work on RCF. If additional facts or data become available that suggest another categorization is appropriate, the matter can be revisited.

[14] Although RCF is very must less durable/biopersistent than amphibole asbestos.

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