



NYCO Minerals, Inc.

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January 24, 2008

To: Whom It May Concern

Re: REACH Status of NYCO wollastonite products

### 1. Updated summary

- a. NYCO wollastonite grades without surface treatment are exempted from REACH registration following Article 2 § 7(b) and Annex V point 7 granting registration exemption to minerals occurring in nature, not chemically modified.
- b. NYCO surface treated wollastonite grades. With support of our industry association (IMA-Europe), NYCO considers these products as "preparations" and as such the unmodified mineral and coating agent need to comply individually (or be exempted) from REACH. NYCO is following-up with our additive suppliers to provide the REACH status of their product(s) that NYCO uses for surface treatments.

Please find further details hereunder.

### 2. The REACH initiative

The European Parliament and the Council have adopted, on 18 December 2006, a new EU regulatory framework for chemicals known as **REACH** (Registration, Evaluation, Authorisation and restriction of **CH**emicals). The REACH Regulation (EC) 1907/2006 has been published in the Official Journal of the European Union on 30 December 2006 and entered into force on 1 June 2007. Amongst other obligations, REACH requires the registration of chemical substances, followed by an evaluation process. In this process the substances on their own, in preparations or in articles are evaluated in respect to health, safety and environmental aspects when manufactured, stored and used. The registration process will stretch over the next 11 years and will be preceded by a pre-registration phase (1 June 2008 – 1 December 2008).

### 3. Minerals and wollastonite under REACH

With respect to minerals, Article 2 § 7(b) and Annex V point 7 explicitly exempt from registration and evaluation "minerals which occur in nature, if they are not chemically modified" because such a registration is deemed inappropriate or unnecessary for these substances and their exemption from these requirements does not prejudice the objectives of this Regulation. **Consequently, wollastonite falls under the scope of this definition and is exempted from registration.** *The "wollastonite" substance applies to all our wollastonite grades without surface treatment.*

### 4. Status of coated minerals under REACH

#### **Description of a coated mineral**

A coated mineral is a surface-treated mineral where the surface treatment results in a two dimensional modification of mineral particles. This modification with a coating agent is solely intended to give a

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specific physicochemical characteristic. NYCO's product line includes surface treated versions of its wollastonite grades.

### Definitions given in Article 3 of the REACH Regulation (EC) 1907/2006

(1) "Substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

(2) "Preparation" means an (*intentional*<sup>1</sup>) mixture or solution composed of two or more substances

Whether a coated mineral is a preparation or a multi-constituent substance or other substance is a matter for assessment by the manufacturer or importer. It is recommended to use the guidance for identification and naming of substances under REACH to do this. This guidance can be downloaded at:

[http://www.ima-reach-hub.eu/index.php?option=com\\_docman&task=cat\\_view&gid=15&Itemid=26](http://www.ima-reach-hub.eu/index.php?option=com_docman&task=cat_view&gid=15&Itemid=26)

[http://reach.jrc.it/docs/guidance\\_document/substance\\_id\\_en.htm](http://reach.jrc.it/docs/guidance_document/substance_id_en.htm)

### Registration duty for coated minerals:

**If a coated mineral has been assessed as a preparation**, then its individual substances (i.e. the unmodified mineral and the coating agent) shall be registered separately by the manufacturer or importer of these substances. This approach is consistent with the European Commission's response to a question about the registration duty of preparations:

*"Registration under REACH is only for substances, not preparations or articles. The substances in preparations and articles are potentially subject to registration."*

**If a coated mineral has been assessed as a substance**, then it should not be registered provided that the use "surface treatment" is described in the registration dossiers of the coating agent and the unmodified mineral, unless the agent and mineral are exempted in Annex IV or V of the REACH Regulation (EC) 1907/2006. This approach is consistent with the European Commission's response to a question about the registration duty of surface-modified substances:

*"The surface treatment of a substance is a two dimensional modification of macroscopic particles. Surface treated substances could not be reported for EINECS. For REACH these substances should also not be registered separately from the unmodified substance as such but the use "surface treatment" should be described in the registration dossiers of the surface treating agent and any other substance used in the process. That means that a substance e.g. carbon black which is surface treated with an agent to avoid the agglomeration of particles or to change the conductivity should not be registered separately. However the use "surface treatment" must be regarded in the dossiers of carbon black and the surface treating agent. Any specific hazards or risks of the treated surface should be appropriately covered by the classification and labeling and by the chemicals safety assessment and resulting exposure scenarios."*

**Consistent with our industry association (IMA-Europe), NYCO considers surface treated wollastonite products to be a "Preparation" for which the individual substances composing the preparation need to be registered (or exempted) separately in REACH.**

<sup>1</sup>The word "intentional" is not written in the legal definition but this clarification has been adopted by the European Chemical Agency in the Technical Guidance Document for identification and naming of substances under REACH (RIP 3.10, page 23, 2nd paragraph : "Preparations, as defined in REACH, are intentional mixtures of substances and are consequently not to be considered as multi-constituent substances").

The findings in previous Health and Safety studies support the decision to consider the surface treated wollastonite as a preparation. It has been shown in In-vivo studies that the solubility / toxicity of the surface modified wollastonite compared to the uncoated wollastonite is the same (e.g. wollastonite per the Fraunhofer-Institut study circa 1993, "Investigation on the durability of wollastonite in rat lungs"). For the surface coated wollastonite, the potential toxicity of the wollastonite and coating agent (i.e. organosilanes) are independent of each other since the potential toxicity of each involves two different mechanisms. The biological interaction of the mineral with cells/tissues involves well understood physicochemical properties, e.g. dose, fiber dimension, durability in tissues and surface activity. Metabolism is not part of the toxicological equation for the mineral. Conversely, the interaction of organosilanes with cells/tissues is chemical in nature involving metabolic processes. Since the toxicity mechanism for the coating agent and mineral are different (metabolic vs. physiochemical), there is no possibility of synergism and it is proper and correct to consider the toxicity of the coating agent and mineral separately when assessing the toxicity of the surface modified mineral.

## **5. Going Forward**

NYCO will continue to closely monitor the development of the REACH legislation by actively working through its industry association (IMA-Europe<sup>1</sup>) and providing stakeholder input into the legislative development process. A REACH compliant Safety Data Sheet (SDS) for wollastonite and surface modified wollastonite is being created and will be posted on the IMA-Europe website. Also, NYCO is currently working very closely with its suppliers to ensure that they are addressing their REACH compliance for the additives that NYCO purchases and uses for surface modification purposes.

NYCO has appointed Messrs. Salvatore LaRosa and Christophe deBellefroid responsibility for REACH implementation. With the assistance of IMA-Europe, this team is assessing the impact of the forthcoming legislation on our business and product portfolio. The objective is to ensure timely REACH compliance and avoid business disruption for our customers. As the REACH regulatory requirements are implemented, NYCO will be taking the necessary action to be in compliance for the products that we supply.

Most Sincerely,



Salvatore LaRosa  
Health Committee Chairperson

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<sup>1</sup> [www.ima-europe.eu](http://www.ima-europe.eu)