MEMORANDUM

Via E-Mail

DATE: November 3, 2009

TO: Clients and Friends

FROM: The Acta Group, L.L.C.

RE: ECHA Publishes Concise Guidance on Chemical Safety Assessment

Today the European Chemicals Agency (ECHA) announced the availability of its *Guidance in a Nutshell: Chemical Safety Assessment*, which is intended to assist industry in understanding the general provisions for conducting a Chemical Safety Assessment (CSA). ECHA states that the Guidance is aimed at non-experts who would like to understand the legal requirements under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation regarding substance assessment. The Guidance provides an overview of what the CSA is and how it is performed and documented. It also outlines the communication needs down the supply chain and the resources required, in terms of time and expertise, to comply with the legal obligations. The Guidance is available on the Internet at http://guidance.echa.europa.eu/docs/guidance_document/nutshell_guidance_csa_en.pdf.

Under REACH, a CSA is required for all substances subject to registration in quantities of ten tonnes or more per year per registrant. A CSA is not required, however, if the substance is present in a preparation and the concentration of the substance in the preparation is below certain concentration limits. Usually the manufacturer or importer of the substance has the duty to carry out the CSA and to document it in the Chemical Safety Report (CSR), as part of the registration process. The CSR of the manufacturer, and therefore the exposure scenarios, needs to cover the manufacturing process and all the identified uses and life cycle stages of the substance. The CSR of the importer must address only the identified uses and the resulting life cycle stages, leaving the manufacturing process out.

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Producers or importers of articles that are required to register a substance under REACH are also required to make a CSA and to document it in a CSR if the substance is present in the articles in quantities of ten tonnes or more per year. The registrant's CSR will address exclusively the use of the substance related to the article and will consider the whole lifespan of the article, including its disposal. The CSR has to be submitted to the ECHA with the technical dossier, as part of the registration process.

The three major steps in the CSA process are hazard assessment; exposure assessment; and risk characterization. The hazard assessment requires the collection and evaluation of all available and relevant information on the substance. The objective of the hazard assessment is to identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels for exposure considered as safe. If, as a result of the hazard assessment, it can be concluded that the substance does not meet the criteria for classification as dangerous or to be considered persistent, bioaccumulative, and toxic (PBT)/very persistent, very bioaccumulative (vPvB), the CSA is complete. If the substance meets any of these criteria, two additional steps are required to complete the process.

The exposure assessment is the process of measuring or estimating the dose or concentration of the substance to which humans and the environment are or may be exposed, depending on the uses of the substance. Within the exposure assessment, the definition of the conditions under which the substance is manufactured and used is critical to determine the levels of exposure. For each exposure scenario, the exposure levels of humans and the environment need to be determined. The exposure scenarios will cover all identified uses and life stages of the substance.

The third step in the CSA process is the risk characterization. For the risk characterization, the levels of exposure are compared with the threshold levels for each effect. Where it is not possible to determine a threshold level for one effect, a qualitative or semi-quantitative approach is used. Risks are regarded as controlled under REACH when the exposure levels to the substance are below the threshold levels considered as safe, both for humans and for the environment. For effects with no threshold levels, emissions and exposures have to be minimized or avoided for risks to be considered to be controlled.

If risks are under control, the CSA ends here. If risks are not under control, the CSA has to be refined, by obtaining more data on the properties of the substance, changing the conditions of manufacturing or use, or making more precise exposure estimations. The CSA is

documented in the CSR and the final exposure scenarios are communicated through the supply chain via the extended Safety Data Sheet.

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We hope this information is helpful. As always, please call if you have any questions.