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VISTA

Interoffice Communication

FROM: T. G. Grumbles
DATE: September 26, 1991

SUBJ: NEW PRODUCT DEVELOPMENT: POLYMERS

The regulatory and product liability issues associated with polymers products are somewhat different than our other business areas but are still significant and must be managed. Vista's New Product Development Process was developed and implemented to manage these issues, but has not been uniformly applied in the polymers business areas. Many of the elements of the process were integrated into the PD&I process, but many of the product changes or developments where regulatory and liability issues are of concern do not go through the PD&I process. We need to develop and formalize a process that is suited to polymers product development to assure regulatory compliance is achieved and product liability issues are addressed.

The system would provide guidance on what types of changes would require documentation of consideration and what questions must be considered at what stage of product development. The intent would be to assure product development can proceed efficiently and in a compliant manner.

Attached is a summary of issues involved in polymers new product development. Dave Penney and I have developed this list to facilitate discussion of this issue and development of a process.

Please provide me with any comments or thoughts you have on this issue. I'll be in touch otherwise as development proceeds.

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POLYMERS PRODUCT DEVELOPMENT ISSUES

TSCA Status All materials produced, or used to produce substances, for commercial purposes must be on the Toxic Substances Control Act (TSCA) inventory. The determination of TSCA inventory status can be done by searching the inventory or obtaining written certification of inventory status from the supplier.

All substances put into a compound must be on the inventory.

Typically, the main concern is status of compound constituents. However, if we are doing anything "in-the-reactor" the polymer may be defined as a new product. A careful review of all "in reactor" modifications is necessary to determine inventory status.

NOTE: All chemicals imported into the united states must be accompanied by specific import certifications. This certification must accompany the shipment or shipment documentation.

Monomer Levels The residual level of monomer materials in our polymers and compounds is a significant issue for multiple reasons. The monomers of concern are those in PVC as well as other blending or alloy polymers such as ABS.

The concerns include product liability warnings, regulatory labeling requirements, level restrictions for certain applications such as food use, and the potential to create workplace exposures in our plants and our customers plants.

Vinyl Chloride, Butadiene, and Styrene are all recognized carcinogens. It is imperative that we know what residual levels are and what workplace levels may be created during processing.

Process Emissions In addition to the monomers mentioned, other processing emissions must be evaluated. These include emissions during normal processing conditions as well as misuse conditions, specifically burning. As new additives and/or alloy materials are used we must develop information, quantitative if possible, on process emissions. Any emissions resulting in odors result in customer questions. We need to be in a position to tell them what smells, even if it is not a hazard.

Regulatory Classifications/Notifications Multiple compounding materials are included on EPA's SARA 313 list. We are required to notify customers who purchase products containing 313 listed materials of that fact and the amounts present.

The waste classification of PVC compounds is determined, at a minimum, by the Toxicity Characteristic Leaching Procedure (TCLP). This is a water leaching procedure that looks for specified levels of some 35 listed materials. Several PVC compound constituents are on the list.

Relatively minor changes in constituent concentrations could change the waste classification of a compound from non-hazardous to hazardous.

Other regulatory warning requirements are found in the OSHA Hazard Communication Standard and multiple state regulations such as California Proposition 65.

Manufacturing Site Impact If new process materials or process modifications are necessary for new product development, the impact of these changes on the manufacturing site must be reviewed. Impacts include permit modifications, emissions impact, waste treatment system impact, employee exposure and hazard communication program changes.

MSDS and Labels (experimental and commercial)

OSHA requires that MSDS's and labels provide appropriate warning information for all hazardous constituents present in products at a level of 2% or more (0.1% for carcinogens). This applies to all products regardless of the volume produced. Consequently, changes in the level or hazard status of formula components can trigger additional warning requirements on product MSDS's and labels. OSHA allows categories of products with similar hazard properties (physical and chemical) to be covered by the same MSDS. However, review of all product changes is required to determine that MSDS's and labels for the category are appropriate in each case.

New Materials - Not used previously by Vista

New materials (resins or additives) present special problems because of the lack of experiential knowledge regarding the toxicological and regulatory status of such materials. Existing or anticipated toxicological and regulatory information can have a significant impact on whether and how these materials are to be used. Careful review of available information is necessary to develop appropriate handling instruction for blenders and assure that current regulatory and health standards are met. A current experience with brominated fire retardants suggests the need for early review of potential toxicity and regulatory issues associated with new materials.

Fire Safety

Despite a wealth of information supporting the fire safety of PVC, this continues to be an active issue. Building codes organizations (NEC an NY) and standard setting bodies (ASTM and UL) are moving to include fire performance and toxicity standards for plastics. Related questions arise regarding exposure to volatile components during molding. Aside from the regulations, product legal considerations warrant full consideration. There may be sufficient data for most formulations, but what about those with new components?