Emerging Compliance Issues for Plastic Drums and IBCs

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Compliance Issues of Plastic Containers

Requirements for Materials of Construction

- Resin selections for DOT compliance
- Additives UV inhibitor
- Food safety compliance
- Religious requirements
- CONEG/California TIP
- REACH
- Deleterious substances
- Other emerging issues

Requirements for Performance of Packaging

- DOT required testing
- NMFC and UFC
- Compatibility evaluation
- Food safety and GFSI
- Fire safety NFPA 30
- Static control NFPA 77
- Regulatory disconnects of transport and storage

Resin Selection for DOT Compliance

DOT standards for **plastic drums** in 49 CFR 178.509 (b) require that packaging must be manufactured from suitable plastic material, and be of adequate strength in relation to its capacity and intended use.

The packaging must be adequately resistant to aging, and to degradation caused by the either the substance contained or by ultra-violet radiation.

Materials of Construction Requirements

Resin Selection for DOT Compliance

DOT standards for **composite IBCs** in 49 CFR 178.707(b) require that inner receptacles be manufactured from plastic material of known specifications, and be of a strength relative to the service it is required to perform.

The material must be resistant to aging, and to degradation caused by UV radiation.

Plastic Resin Equivalency Principles

DOT has been engaged in a discussion with the plastic drum and composite IBC trade organizations through the Industrial Packaging Alliance of North America (IPANA), which includes both the Plastic Drum Institute (PDI) and the Rigid Intermediate Bulk Container Association (RIBCA).

The issue of resin equivalency is being addressed through manufacturing process and physical property comparisons, and categorization of plastic drum and IBC receptacle resins.

Plastic Resin Equivalency Principles

Resins offered by material manufacturers are categorized primarily by density and melt flow, and equivalency is proven through design type performance testing by container manufacturers.

The U.S. industry has three general categories of large part blow-molding HDPE resins developed based on density and melt flow, other physical properties, processing characteristics, and finished package testing.

Additives for Plastic Drums and IBCs

DOT standards for plastic drums in 49 CFR 178.509 (b) and for IBCs in 49 CFR 178.707 (b) also require that plastic packaging must be adequately resistant to aging from UV radiation by use of carbon black, or other suitable pigments or inhibitors.

The expected life of the drum or IBC receptacle dictates additive concentration. Guidance for plastic drums is found in 49 CFR 173.28, and in 49 CFR 180.352 for IBC plastic receptacles.

Materials of Construction Requirements

Materials of Construction for Food Use

DOT regulations on use of UN marked packaging for food use are generally silent.

For competent authority approval use of recycled resins, DOT requires a marking of "DO NOT USE FOR FOOD OR DRINK", with size of letters in 49 CFR 178.3.

For poisonous materials, as defined in 49 CFR 173.132, each non-bulk packaging must be marked by the word "POISON", per 49 CFR 172.313 (b) with a size minimum alsopspecified ackaging LLC, 2013

Materials of Construction for Food Use

FDA routes to compliance for materials of construction for include direct reference in 21 CFR, generally recognized as safe (GRAS), prior sanctioned, or permissible through the Food Contact Notification system (FCN) of the FDA.

Packaging materials are considered to be an **indirect** food additive.

Use limitations of packaging materials are also specified in FDA regulations.

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Review of FDA Materials of Construction

High-density high molecular weight polyethylene is the primary large part blow-molding material for plastic drums and composite IBC receptacles, and must be compliant with 21 CFR 177.1520 for food use.

Antioxidants and stabilizers must be compliant with 21 CFR 178.2010.

Colorants, except for non-FDA black, must be in compliance with 21 CFR 178.3297.

Gaskets in closures, valves, and dispensing systems must be compliant with 21 CFR 177.2600, or other material reference.

Religious Requirements for Food Safety

The requirements of Kosher and Halal are generally met if food product contact materials of plastic drums and composite IBC receptacles are known to not have animal derivation.

Certification by religious organizations are typically limited to customer specific contractual obligations.

Materials of Construction Requirements

Transmissible Agents of Animal Origin

The requirement for materials of construction to not have animal derivation also meet the need for assurance against bovine spongiform encephalopathy agents, referred to as BSE and TSE.

Such transmissible agents are resistant to process temperatures and risk minimization is the proper approach to compliance.

Heavy Metals in Packaging

Heavy metals, specifically cadmium, hexavalent chromium, lead, and mercury, have been targeted as deleterious components of packaging by governments at the state level in the U.S.

CONEG Model Legislation, California Toxics in Packaging Legislation, and the Toxics in Packaging Clearinghouse are legislative requirements for packaging materials not to exceed 100 ppm heavy metal sum concentration, and that such substances not be intentionally added by packaging manufacturers in the converting process of the raw materials of construction.

Compliance with the above legislation correlates with EU ROHS requirements for the awy protectal sLC, 2013

Materials of Construction Requirements

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

The purpose of the EU driven REACH regulation is to ensure a level of protection of health and environment. REACH requires the registration of substances that are manufactured in or imported into the EU. Different rules apply, however, to imports of articles. Packaging is considered an article. An article requires registration if it contains a substance that is intended to be released under normal or reasonably foreseeable conditions of use. Plastic drums and IBCs are exempt from registration as such.

An article requires notification under the REACH Regulation if an article contains a substance on the latest candidate list of Substances of Very High Concern (SVHC List) and the substance is present in the article in concentrations greater than 011 percent by weight.^{Property of Greif Packaging LLC, 2013}

Is an MSDS required for packaging?

The OSHA regulations, in 29 CFR 1910.1200(g), require that an MSDS be supplied for any (hazardous) chemical provided by a manufacturer or importer.

However, "articles" are specifically exempted from this requirement, in 29 CFR 1910.1200(b)(6).

Since packaging is defined as an article in 29 CFR 1910.1200(c), an MSDS is not appropriate or necessary for a plastic drum or IBC.

Deleterious Substances

The list of deleterious substances that are of interest in packaging materials include, but are not limited to the following:

 quaternary ammonium compounds, melamine, benzophenone, chlorinated compounds, polybrominated biphenyls or polybrominated diphenyls, fumigants, pesticides, preservatives, biocides including dimethylfumarate, perfluorooctane sulfonates or perfluorooctanoic acid, bisphenol A, phthalates or phthalate esters including DOP or DEHP, latex, common

Ifood allergens... Property of Greif Packaging LLC, 2013

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DOT Required Testing – Plastic Drums

Plastic drums, marked as UN 1H1 (tight head drums) and 1H2 (open head drums) are classified as non-bulk packagings. Testing of non-bulk packagings is specified in Part 178, Subpart M, of DOT regulations in 49 CFR.

General requirements of non-bulk testing in 49 CFR 178.601 include design type, periodic, and production testing, definition of different packagings and variations.

Test reports must be maintained for each design type.

DOT Required Testing – Plastic Drums

The non-bulk testing protocol includes the following:

Drop test – 49 CFR 178.603 Leakproofness test – 49 CFR 178.604 Hydrostatic pressure test – 49 CFR 178.605 Stacking test – 40 CFR 178.606 Vibration standard – 49 CFR 178.608

DOT Required Testing - IBCs

Composite IBCs, marked as UN 31 HAI, are classified as intermediate bulk packagings. Testing is specified in Part 178, Subpart O, of DOT regulations in 49 CFR.

General requirements of intermediate bulk containers include design type, periodic, and production testing, and definitions IBC components and different design types.

Test reports must be maintained for each design type. Property of Greif Packaging LLC, 2013

DOT Required Testing - IBCs

The composite intermediate bulk testing protocol includes

a consecutive series of tests on a single container in order:

Vibration test – 49 CFR 178.819 Bottom lift test – 49 CFR 178.811 Stacking test – 49 CFR 178.815 Leakproofness test – 49 CFR 178.813 Hydrostatic pressure test – 49 CFR 178.814

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 A second container drop test as specified in 49 CFR

NMFC and UFC

The National Motor Freight Classification (NMFC) is an agency of the American Trucking Association. The Uniform Freight Classification (UFC) is an agency of the Association of American Railroads. Both agencies have interests in packaging specifications, truck and railcar loading, bracing, and claims.

NMFC and UFC have set minimum plastic drum construction and performance specifications that are related to the capacity and weight to be contained.

Performance testing of containers are detailed in published

NMFC and UFC

When packaging a non-hazardous liquid product in a tight head plastic drum NMFC and UFC require that the container meet the construction specifications for thickness.

NMFC and UFC also demand that tight head liquid drums satisfy four performance standards - drop, static compression, vibration and hydrostatic pressure tests. Open head drums require a tip over and drop test.

Compatibility Evaluation

Chemical compatibility evaluations and recommendations start with an MSDS review. MSDS information must include transport information. Hazardous materials must be identified according to the table in 49 CFR 172.101.

Compositional information and physical property detail of the hazardous material is needed as part of the compatibility evaluation. Mixtures may require special consideration.

Compatibility Evaluation

For plastic containers, DOT provides compatibility evaluation requirements of the filler in 49 CFR 173.24 (e).

This is to ensure that plastic packaging is compatible with the lading. The requirements include consideration of corrosivity, permeability, softening, premature aging, and embrittlement. Accelerated aging guidelines are provided.

Packaging manufacturers supply small scale test bottles, made from drum and the for the sins, for

UN – GHS Harmonization

Two classification systems exist for hazardous materials.

The UN Recommendations on the Transport of Dangerous Goods (UN Model Regulations) is focused on hazardous material transport conditions and assignment of packing groups.

The GHS (Globally Harmonized System) of Classification and Labeling of Chemicals is focused on defining health, physical and environmental hazards of Property of Greif Packaging LLC, 2013

UN-GHS Harmonization

There are differences in the definitions for corrosives in the two classifications systems

UN Model Regulations define Class 8 corrosives as substances which cause severe damage when in contact with living tissue, or in the case of leakage will damage other goods, or the means of transport.

GHS has a different definition of skin corrosion. Both in vivo (animal and human data) and in vitro test methods are used to define skin corrosion

UN-GHS Harmonization

The existing working relationship between the two classifications systems is as follows:

UN PG I = GHS Category 1A UN PG II = GHS Category I B UN PG III = GHS Category 1C

UN-GHS Harmonization

Corrosive Mixtures – The Focus Area

UN: Little advice for the classification of mixtures, packing group assignment is based on length of time of contact necessary to produce full thickness destruction of skin, and there is little to no consideration for concentrations

GHS: Detailed advice on classification of mixtures. Makes use of rules for concentration and dilution of mixtures, and interpolations – referred to as bridging principles. Concentration limits are used where bridging principles do not apply

UN-GHS Harmonization

A joint UN-GHS group is working on the differences in corrosive mixture classifications. The definition of skin destruction is one area that needs to be harmonized.

Hazard classes for corrosive exposure may need to be different from transport conditions.

The concept of bridging principles for mixtures could be used in UN Model Regulations with Competent Authority oversight.

Food Safety and GFSI

In the late 1990's, the safety of our global good supply chain began to get the attention of stakeholders ranging starting with growers and processers, retailers, and consumers.

The Global Food Safety Initiative (GFSI) was started in 2000 for the continuous improvement of food safety systems, covering all scopes of the global food supply chain from field to fork, worldwide.

Packaging is being considered by food processors and fillers to be a vital component in the food safety Property of Greif Packaging LLC, 2013 system.

Food Safety and GFSI

GFSI has recognized a number of food safety management schemes. Certification according to a GFSI recognized scheme can be achieved through a successful third party audit against any of the following schemes recognized by the GFSI:

BRC Global Standard for Food Safety

Canada GAP (Canadian Horticultural Council On-Farm Food Safety Program)

FSSC 22000 Food Products

Global Aquaculture Alliance Seafood Processing Standard

GLOBALG.A.P.

Global Red Meat Standard (GRMS)

IFS Food Version 6

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Primus GFS Safe Quality Food

Food Safety and GFSI

The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

Good Manufacturing Practice (GMP) is a regulatory requirement of the FDA for food manufacturers, fillers, packagers, and retailers. The foundation of food safety is a robust GMP program. Packaging manufacturers are being required to implement a GMP program at minimum. ³³ Property of Greif Packaging LLC, 2013

Food Safety and GFSI

The mechanism that ensures a robust GMP program is HAACP (Hazard Analysis and Critical Control Points).

HACCP is a systematic preventive approach to food safety, including biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe.

HAACP practitioners are being employed to lead packaging manufacturers towards food safety Certification. Property of Greif Packaging LLC, 2013

Fire Safety and NFPA 30

National Fire Protection Association (NFPA) is an organization that develops standards for fire and safety issues. NFPA sets standards but does not enforce the standards.

NFPA 30 is a code for flammable and combustible liquid storage, both in warehouses and operations. Enforcement is up to local fire jurisdictions, risk assessors and insurers.

The 2012 edition of the 30 Code is being enforced. 35

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Fire Safety and NFPA 30

Who follows NFPA codes and guidance?

- Chemical manufacturers who operate under the umbrella of responsible care in product stewardship and safety.
- Factory Mutual relies on "standards of care" over code enforcement.
- Code enforcers are local fire jurisdictions, i.e. fire marshals, fire inspectors, emergency personnel
- Industrial risk insurers also enforce the code.
- Building construction and fire protection engineers, and component manufacturers.
- Packaging and container manufacturers.

Fire Safety and NFPA 30

NFPA 30 is one of the most talked about fire codes in packaging. The 30 Code addresses flammable and combustible liquid storage in the following containers:

Metal containers, including steel pails, drums, and IBC's

Plastic containers, including drums and composite IBC's

Fibre drums, i.e. Liquipaks, composites

Smaller size containers made out of metal, glass, plastic etc

Fire Safety and NFPA 30

- Flammable liquids are the defined as having a flash point below 100F
- NFPA classifies flammables by flash point into Class I liquids, with Class IA, IB, and IC subgroups
- Combustible liquids are defined as having a flash point above 100F
- NFPA classifies combustible liquids by flash point into Class II and Class III, with Class IIIA and IIIB subgroups, depending on flash point
- Class IIIB are not regulated by UN/DOT

Fire Safety and NFPA 30

- Protected storage in NFPA 30 refers to the combination of "fire" protection schemes, sprinkler protection criteria, and container designs needed to maintain a given level of safety and insurance coverage
- Unprotected storage in NFPA 30 refers to the absence of fire protection, or inadequate protection
- Unprotected storage includes uninsured, uninsurable, and selfinsured buildings, as well as outdoor storage

Static Control and NFPA 77

The generation of undesirable static electricity in solid, liquids, and gases, and also on persons, gives rise to the need to quantify and control it in the materials of use.

Materials become charged when there is an excess or a deficiency of electrons relative to the neutral state. In materials that are conductive, electrons move freely, allowing the flow of an electric charge. In materials that are insulators, electrons are not free to move, resisting the flow of an electric charge. Materials of use are typically quantified by their resistivity.

Static Control and NFPA 77

There are two types of measurements of resistivity, volume and surface.

Volume resistivity is the measurement of resistance in a body of unit length and unit cross sectional area.

Surface resistivity is the measurement of resistance across opposite sides of a surface of unit length and unit width, expressed in ohms (ohms/square).

Static Control and NFPA 77

Conductive materials have the ability to allow the flow of an electric charge when in contact with earth, and possess a volume resistivity less than 10e4 ohm-meters.

Electrostatic dissipative materials are incapable of retaining a significant amount of electric charge when in contact with earth, and possess a volume resistivity greater than 10e4 ohm-meters and equal to or lower than 10e9 ohm-meters, or a surface resistivity less than 10e10 ohms at ambient temperature and 50% humidity.

Static Control and NFPA 77

The term antistatic is used to describe a material that is capable of dissipating an static electric charge at an acceptable rate when in contact with earth, and is often used as a generic term in place of conductive and static dissipative material properties.

Most materials used in packaging of hazards are highly electrically insulating, tend to become charged, and may result in brush or spark discharges. Performance requirements for rigid containers are more difficult for experts to define than for flexible containers, especially with flæmmable hazards Property of Greif Packaging LLC, 2013

Static Control and NFPA 77

Two standards have been in place to provide guidance in static control of packaging - NFPA 77 for the US and Canada, and Cenelec TR 50404:2003 for Europe.

A new ANSI standard is being developed that will be part of a global IEC document.

NFPA 77 is guidance document that is currently undergoing a 2013 revision.

The Regulatory Disconnects

The industry has identified one area of regulatory compliance and safety that may require the attention and action of collaborative working groups.

DOT transport regulations in 49 CFR, as harmonized with the UN Model Regulations, are primarily focused on transport issues of packaging with hazardous materials, and generally silent of issue of packaging use and storage.

The guiding reference for transport is 49 CFR 172.101. ⁴⁵
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The Regulatory Disconnects

A disconnect has been identified for selection and use of packaging as allowed for transport, based on regulations in 49 CFR and the UN Model Regulations, and what can be safely used in operations and protected in storage.

It may benefit our industry if the regulatory documents and flow charts for transport could be cross-referenced and unified with the codified and recommended practice documents for fire safety and static control, to provide fillers and users of plastic container proper guidance. Property of Greif Packaging LLC, 2013