



Environmental, Health and Safety Specification for Articles and Chemical Products or their Components

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1.0 Purpose:

The purpose of this specification is to:

- Communicate the chemical and article specification requirements to suppliers.
- Establish the process for exchanging chemical and material data between suppliers and Carestream Health, Inc. (“Carestream”) to ensure the sale of regulatory compliant products worldwide.

2.0 Scope:

This specification applies to:

- all Carestream articles and chemical products provided by the Supplier
- components and packaging-related product components the Supplier provides to Carestream, which Carestream uses to manufacture articles or chemical products

3.0 Definitions:

Articles – An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

Examples of articles include film, paper and screens

Articles also include Packaging-Related Product Components - A part or constituent of the sales unit that is essential to the use of the product for its intended purpose or application. Examples of packaging-related product components include: film cassettes, film bags, labels, processing chemistry bottles.

BOMcheck – An industry-wide initiative using a regulatory compliance tool designed specifically to enable suppliers to provide declarations for REACH, RoHS and other restricted substances legislation.

Chemical Products - Products made of organic or inorganic substances with a distinct molecular composition, which can be a solid, liquid or gas. Products may be individual chemicals or chemical mixtures. Chemical products are typically consumed during use. Examples of chemical products include photochemicals, screen cleaners and imaging agents.

Components of Articles or Chemical Products - Raw materials used to manufacture articles and chemical products. Examples include film or paper base, solvents, lubricants, polymers and chemical raw materials.

4.0 Specification Requirements:

The Supplier must evaluate all constituents in the Article, Chemical Product or Product Component to ensure that the following Environmental, Health & Safety (EHS) Product Specifications are met. Section 5.0 identifies the process that Suppliers must use to verify that their product meets these requirements.

4.1 Material Composition Requirements:

Products supplied to Carestream must be in compliance with national and international regulations. Restricted materials must be declared when present above a regulatory limit.

4.2 Safety Data Sheets (SDS): The Supplier is required to provide a SDS for chemicals, solutions or mixtures to the Carestream purchasing representative and to:

ww-ehs@carestreamhealth.com. The SDS must comply with applicable provisions of the OSHA 2012 Hazard Communication Standard 1910.1200, or the comparable regulation for the country where the material is transported. The OSHA Standard and many other country regulations require hazards to be classified by the Global Harmonized System of Classification and Labeling of Chemicals. The SDS must be provided in English, but may be required in other languages if the Supplier provides material to countries outside the US.

4.3 Chemical and Product Registration Requirements:

The Supplier is required to confirm chemicals, solutions, mixtures or chemicals that may be released from articles during foreseeable use comply with all applicable chemical registration and premanufacture notification requirements in those countries that have enacted such requirements. Countries having chemical control regulations include, but are not limited to, Australia (AICS), Canada (CEPA), China (SEPA), Europe (REACH), Korea (ECL), Japan (METI), New Zealand (NZIoC), Philippines (PICCS), Province of Ontario, Switzerland, Taiwan (TCSI) and US (TSCA). The Supplier is required to confirm biocides/biostats/pesticides contained in articles and chemical products comply with all applicable requirements in those countries that have enacted such requirements. Countries having established biocide directives include, but are not limited to, Canada (PCA), European Union (Biocide Products Directive) and US (FIFRA).

4.4 Pulp and Paper:

Paper products must be manufactured using renewable pulps derived from managed natural regeneration forests and plantations. Suppliers should declare any chain-of-custody or third-party certification of the origin of pulp and paper (e.g. Forest Stewardship Council or Programme for the Endorsement of Forest Certification).

4.5 Emissions from Products:

The Supplier must identify airborne emissions that may be generated/emitted during normal conditions of use or foreseeable misuse (e.g., volatile organic compounds, carbon black, ozone, styrene, objectionable odors and dust).

4.6 Composite Wood:

Products and some packaging materials constructed of hardwood plywood, particleboard, and medium density fiberboard must be tested, certified, and labeled as required to demonstrate compliance with the formaldehyde emissions standards, as specified in the California Air Resource Bureau (CARB) Airborne Toxic Control Measure to Reduce Formaldehyde Emissions From Composite Wood Products. The list of mills that have been identified by a CARB-approved Third Party Certifier as producers of CARB compliant composite wood products can be found at: <http://www.arb.ca.gov/toxics/compwood/tpc/listofmills.htm>. Imported wood packaging should meet the applicable regulatory standards, e.g. ISPM No. 15.

4.7 Product Safety (PS):

Articles must conform to all applicable Product Safety (PS) standards appropriate for intended markets such as Flammability (UL-94). Upon request, certificates, test reports and supporting documentation must be provided for all countries in which the Supplier has approval to market.

4.8 Marking of Plastics:

Plastic parts with a mass greater than 25 grams must be marked per ISO Standard 11469 (Plastics - Generic identification and marking of plastics products). Exceptions include when plastic parts have dimensions that make marking impractical (e.g., long, thin parts that lack adequate surface area to create a legible mark) or for applications where marking will interfere with functionality.

4.9 Other Required Information:

The Supplier is required to provide the following information when available or obtain the information if specified by Carestream in the Product Requirements Document (PRD) or similar document.

4.9.1 For Articles and Chemical Products

4.9.1.1 Mutagenicity Test Data (e.g., Ames Assay) on individual chemical(s) or on components of articles or chemical products

4.9.1.2 Waste classification for product disposal and basis of classification

4.9.1.3 Evidence of compliance with ISO 10993 for medical device biocompatibility.

4.9.2 For Articles

4.9.2.1 Support Material Identification (e.g., paper, fabric, polyethylene film and high impact polystyrene cartridges)

4.9.2.2 Recycled Content in Paper and Plastic Products

4.9.3 For Chemicals, Solutions or Mixtures

4.9.3.1 pH

4.9.3.2 Worldwide transportation classification (e.g., US Department of Transportation (DOT) or International Air Transport Association (IATA))

4.10 Manufacturing Requirements:

The Supplier must obtain and maintain any necessary approvals and authorizations from regulatory agencies and other government organizations to manufacture in and export from their country of manufacture.

4.11 Product Packaging Requirements:

The Supplier must ensure that packaging materials for Articles, Chemical Products and Product Components meet Carestream EHS Product Specifications for Packaging and Packaging Components see *Packaging Supplier Declaration* and *Instructions* which are located at: www.carestreamhealth.com/ehs-supplier-expectations.html.

5.0 Supplier Verification Requirements:

The Supplier is expected to verify conformance and/or document any exceptions to EHS Specifications outlined in Section 4.0 using BOMcheck. Upon entering into an agreement with Carestream to supply an Article or Product Component, the Supplier must go to Carestream's website at: www.carestreamhealth.com/ehs-supplier-expectations.html for instructions on using BOMcheck.

6.0 Product Changes, Discontinuance, Recalls or Non-Conformance:

The Supplier is obligated to communicate in writing to Carestream EHS at: ehs@carestreamhealth.com, any changes that could impact the safety, health or environmental performance of a Carestream product (including the discontinuance or recalls of products or components). If potential safety, health, environmental or regulatory issues are discovered by Carestream or Carestream's customers, which are determined to be the Supplier's responsibility, the Supplier will be notified in writing. The Supplier must respond in writing within 10 business days to all such notifications. For Contract Manufacturers, this includes taking immediate steps to address the issue for any work-in-process

7.0 Document History

Revision	Section	Reason for Change	Date
2	3.0, 4.1, 4.2, 4.1,4.3	Full document review and update	6/12/2015