FAQ for Suppliers Material Compliance System

Q1. What is the CSH Supplier Materials Compliance System (SMCS)?

A1. Carestream must be able to gather and to report on materials that are present (or not present) in products sold. The SMCS is a comprehensive business approach to deal with suppliers, new product designers, manage engineering changes, and demonstrate compliance to regulations concerning materials used in our products, both for RoHS and REACH.

Q2. What is Benchmark ESG™ Gensuite®?

A2. Benchmark ESG™ Gensuite® is a comprehensive cloud-based software suite that enables companies to implement robust cross-functional Environmental, Social, and Governance (ESG) Solutions. **Benchmark ESG™ Gensuite®** includes a free and easy regulatory compliance software tool to manage declarations for RoHS, REACH, and other restricted substance legislation.

Q3. Why does Carestream want us to use Benchmark ESG™ Gensuite®?

A3. Carestream must meet RoHS2 and REACH regulatory requirements in countries which we market product. Carestream needs our suppliers to provide declarations to identify whether there are restricted materials in their parts. Carestream adopted Benchmark ESG™ Gensuite® software to track our supplier's declarations. This software is free and easy for our suppliers to use.

Q4. What hazards substances are restricted under RoHS2?

A4. Six (6) hazardous substances (Cd, Pb, Hg, Cr(VI), PBB, PBD) were originally restricted by RoHS (2002/95/EC); the RoHS recast Directive (2011/65/EU) incorporated these restrictions for "medical devices" and "industrial monitoring and control equipment" effective July 22, 2014.

Four (4) new hazardous substances (DEHP, BBP, DBP, DIBP) were added by the amended EU Directive RoHS2 (2015/863/EU) and are effective for "medical devices" and "monitor and control equipment" on **July 22, 2021**.

Q5. What do we have to do to be RoHS2 compliant?

A5. Suppliers must determine whether their parts/products contain any of the ten (10) RoHS restricted hazardous substances above the maximum permitted concentration and if yes, determine whether there is an applicable exemption that allows use above the maximum permitted concentration.

Suppliers must provide declarations to Carestream for each part/product to document whether or not it contains one or more of the ten (10) hazardous substances above the allowable level, and if yes, identify the exemption that allows use of the hazardous substance at that level.

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Q6. What hazardous substances are restricted under REACH as an SVHC?

A6. Substances that may have serious and often irreversible effects on human health and the environment can be identified by REACH as Substances of Very High Concern (SVHCs). Chemicals are added to the list of SVHCs twice yearly. The most recent list of SVHCs may be found on the European Chemicals Agency website: https://www.echa.europa.eu/candidate-list-table .

Q7. How are SVHCs regulated?

A7. If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List. Also, under the Waste Framework Directive (WFD) **beginning 5 January 2021**, companies supplying articles containing SVHCs in a concentration above 0.1% weight by weight (w/w) on the EU market have to submit information on these articles to ECHA via the EU SCIP Database.

Q8. What do we have to do to be REACH compliant?

A8. Suppliers must review the list of SVHCs https://www.echa.europa.eu/candidate-list-table and determine whether their parts/products contain any SVHC above 0.1% weight by weight (w/w). Suppliers must provide declarations to Carestream for each part/product to document whether each parts/product contains an SVHC above 0.1% weight by weight (w/w), and if yes, identify the SVHC(s), list the approximate concentration of the SVHC(s) in the part/product, and list the weight of the part/product.

Q9. Why can't our company just state we are compliant under REACH?

A9. Parts/Products may contain an SVHC and still be compliant as long as Carestream completes required SCIP reporting. Therefore "compliant" does not state whether there are SVHCs above the restricted level; Carestream must have a definite "yes" or "no" response.

Q10. Why are we being asked to provide a REACH declaration when our company already provided a REACH declaration last year?

A10. SVHCs are added twice yearly. Periodically Carestream must receive from Supplier revised REACH declarations so that Carestream will know whether parts/product contain the new SVHCs so that Carestream may determine whether we must report (or update) the European SCIP database form for product(s) that contain Suppliers parts/product.