Kodak Alaris Environmental, Health, and Safety

Specifications for Products, Parts, and Packaging

2024 Version 5

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1. [Purpose](#Purpose)

Kodak Alaris expects that products supplied to us will meet all applicable legal requirements during manufacture, distribution, and sale. Supplier products may also be required to meet additional Kodak Alaris requirements that go beyond compliance in order to reduce the environmental impact of our products.

1. [Scope](#Scope)

This document and the corresponding Kodak Alaris Supplier Declaration Form apply to all products supplied to Kodak Alaris and the materials used to manufacture these products, regardless of production location. The Kodak Alaris Supplier Declaration Form (DF) specifies Environmental, Health, and Safety (EHS) requirements for the following types of products:

* Electrotechnical products
* Articles
* Chemicalproducts
* Packaging
1. [Supplier Responsibilities](#Supplier)

### Manufacturing/Export approvals:

### The Supplier shall 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.

### Conformance Documentation:

### The Supplier is expected to complete the Kodak Alaris EHS Supplier Declaration Form (DF) in order to document product conformance for all products supplied to Kodak Alaris.

* 1. **Expectations Regarding Second and Third Tier Suppliers:**

The Supplier is responsible for contacting their suppliers to ensure accurate and complete information is provided to Kodak Alaris. Documentation and/or test data, including documentation and data from the Supplier’s supply chain, shall be available upon request by Kodak Alaris.

* 1. **Product Changes, Discontinuance, Recalls or Non-Conformance:**

 The Supplier is requested to inform Kodak Alaris via email (ehs-questions@kodakalaris.com) of any changes, discontinuance, recalls, or non-conformance that could impact the safety, health or environmental performance of a Kodak Alaris product .

1. [Definitions](#Definitions)

***Articles*** – Manufactured items that are formed to a specific shape or design, which have an end-use function in whole or in part dependent on their shape or design but does not require alternating or direct electric current to operate. Examples of Articles include films and papers, etc. *Note: Although electrotechnical products (equipment) and packaging are technically complex object made from component articles, Electrotechnical Products (including batteries) and Packaging are addressed in their own respective sections.*

Articles also include ***Packaging-Related Product Components*** *(see definition)*.

***Chemical Products*** – Products or raw materials made of organic or inorganic substances with a distinct molecular composition, which can be a solid, liquid or gas. Chemical products may be hazardous or non-hazardous and either individual chemicals or mixtures. Chemicals contained in articles e.g. inks or toners in cartridges which are typically consumed during use are also in scope of Kodak Alaris’ Chemical products definition.

***Conflict* *Minerals*** – Conflict minerals are raw materials or minerals that originate from parts of the world where conflict is occurring (tantalum, tin, tungsten, gold, and their derivatives).

***Electrotechnical Products*** – Devices that require alternating or direct electric current to operate. Finished Electrotechnical Products include printers, scanners, order stations, external power supplies, etc. Components and accessories e.g. printed circuit boards, cables, cords, paper trays, etc. used to assemble equipment products and/or systems are also within scope of Kodak Alaris’ Electrotechnical definition.

***Homogeneous Material*** –A material that cannot be mechanically disjointed into different materials. The term homogeneous is understood as of uniform composition throughout. Examples of homogeneous materials would be individual types of plastics, ceramics, glass, metals, alloys, paper board, resins, and coatings. The term mechanically disjointed means that the materials can be, in principle, separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

***Intentionally added*** –Deliberate use in the formulation of a product where its continued presence is desired to provide a specific characteristic, appearance, or quality.

***Known to be present* –** Supplier has knowledge that the material is present through existing analytical information, second tier supplier declarations or other methods.

***Packaging*** – Any material intended to be used for the containment, protection, handling, delivery and presentation of goods from raw materials to processed goods from the producer to the user or consumer as defined by the European Parliament and Council Directive EU 2018/852 on Packaging and Packaging Waste. Packaging may be classified as primary packaging, grouped or secondary packaging, and transport or tertiary packaging.

***Recycled Content*** – The concentration (% wt/wt) of materials that have been recovered or otherwise diverted from a waste stream, either during the manufacturing process (pre-consumer) or after the consumer use (post-consumer) and have been reused in the production of another product.

***Rigid Plastic Packaging Container (RPPC)*** – Any plastic package having a relatively inflexible finite shape or form that has a minimum capacity of eight fluid ounces (236.6 milliliters), or the equivalent volume, and a maximum capacity of five fluid gallons (18.9 liters), or the equivalent volume, and is capable of maintaining its shape while holding other products. RPPCs include, but are not limited to bottles, cartons, pails, clamshells, and other receptacles.

***Threshold level*** –Concentration level (% wt/wt) which defines the limit above which the presence of a substance in a product shall be declared.

1. [Electrotechnical Product Requirements](#Electrotechnical)

The Supplier shall evaluate ***Electrotechnical Products*** to ensure the following EHS Product Specifications are met.

* 1. **Restricted and Declarable Materials:**

A list of restricted and declarable materials is maintained by the International Electrotechnical Commission (IEC) in standard [**IEC 62474**](https://std.iec.ch/iec62474/iec62474.nsf/).

This list includes restricted materials, reportable applications, and threshold levels for global markets (e.g., EU RoHS, EU REACH, EU POPs, US TSCA, etc.).

*Reference substances* (also part of IEC 62474, at the same web address) contains an expanded listing of these materials, which includes available Chemical Abstract Services (CAS) numbers.

Unless Kodak Alaris has confirmed acceptability for use and provided written permission to a Supplier, products shall not contain restricted materials above the prescribed thresholds for the reportable applications listed in [**IEC 62474**](https://std.iec.ch/iec62474/iec62474.nsf/). It is acceptable to use a [**RoHS**](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015L0863) material if the use is an approved [**EU RoHS exemption**](https://echa.europa.eu/exemptions-art-4-restrictions-rohs) which should be listed on the *Kodak Alaris EHS Supplier Declaration Form (DF).* For components of Kodak Alaris document scanners, no intentional use of cadmium is permitted (EPEAT IE-4.1.2.1).

Suppliers are required to declare if mercury is intentionally added, to ensure Kodak Alaris can comply with applicable regulations.

Suppliers are required to declare the presence of Conflict minerals (tantalum, tin, tungsten, gold, and their derivatives).

Also, Suppliers are required to declare SVHC (Substances of Very High Concern) present at greater than 0.1% wt/wt (1000 ppm). SVHC are identified on the “Candidate List” in Annex XIV of the European Chemical Agency Article 59(1) of the Regulation (EC) No. 1907/2006 (European Union REACH). The SVHC list is found at: <https://echa.europa.eu/candidate-list-table> on the European Chemical Agency website.

* 1. **Safety Traceability Requirements for Critical Components:**

Suppliers providing plastics, foam, wire harnesses, circuit boards and safety labels, used to manufacture a product that will be certified by an independent product safety certification organization (e.g. UL, TUV, Intertek, Nemko), shall meet the minimum safety traceability requirements. [Appendix A](#Appendix_F) identifies these requirements. Meeting these requirements will demonstrate to regulatory inspectors that the material and/or part is identical or equivalent to what is listed in the agency's product safety inspection report.

* 1. **Batteries:**

Suppliers shall ensure that batteries meet applicable regulatory requirements (e.g., EU battery regulation (EU) 2023/1542, US Reese’s Law (16 CFR § 1263.3), etc.) and are labeled properly (e.g., CE mark). In addition, suppliers shall supply the following battery information:

* Safety Data Sheet/Article Information Sheet Product Specification Form (in US English and EU English as a minimum)
* Battery chemistry
* Number and weight of embedded or non-embedded batteries shipped with the product
* Form factor (shape)
* Presence of conflict minerals (tin, gold, tungsten, or tantalum)
* Presence of mercury, lead, cadmium, chromium, polybrominated biphenyl (PBB), polybrominated diphenyl ethers (PBDE), perchlorates, lithium
* Presence of SVHCs above 0.1% wt/wt (1000 ppm)
* Whether primary (non-rechargeable) or secondary (rechargeable)
* Watt hours
* Transportation classification (e.g., UN 38.3 Test Summary)
* Test reports and/or certifications (e.g., UN Safety Test Certificate, Korea Product Safety Testing Certificate)
	1. **Finished Electrotechnical Product Requirements:**
		1. **Product Safety (PS), Electromagnetic Compatibility (EMC) and Radio:** Upon request, applicable certificates, test reports and supporting documentation shall be provided.

Manuals or guides shall be provided which identify appropriate preventative and protective measures to be employed to mitigate risk to customers and service personnel during installation, use and service.

[Appendix B](#_Appendix_B_–) includes references to international regulations and standards regarding Product Safety. This is not a complete list of requirements.

* + 1. **Sound:** Products shall conform to sound pressure levels that may be specified in the Product Requirements Document (PRD). General office systems shall be less than 70 dB(A)**.** Information Technology and Telecommunications Equipment sound pressure levels shall be measured according to ISO 7779. Measured noise levels should represent the full system configuration offered for sale. Products that are part of a network application (printers, accessories) are to be tested in the confines of that application.
		2. **Energy Efficiency:** Products shall conform to all applicable energy efficiency regulations including testing, labeling and registrations applicable to the equipment type and the intended markets. Additional detail regarding product specific efficiency requirements and criteria (e.g. ENERGY STAR ™) may be included in the PRD.
		3. **Emissions from Products:** Suppliers shall 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, dust, etc.). Upon request, certificates, test reports and supporting documentation shall be provided.
		4. **Paper and Printed Materials**: Pulp and paper products shall be sourced from legally harvested forests. Suppliers shall have a process for determining the origin of all pulp and paper products and make this information available to Kodak Alaris upon request.
		5. **Safety Data Sheets (SDS):** Where chemical solutions or mixtures are used with equipment components or spare parts (i.e. paints, cleaning solutions, coolants) the supplier shall provide an SDS. See Section 7.1 for further details.
1. [Article Requirements](#Article)

The Supplier shall evaluate *Articles* to ensure the following EHS Product Specifications are met.

If the article/component supplied falls under the definition of an electrotechnical product (as defined in Section 4.0), refer to Section 5.0 Electrotechnical Product Requirements.

* 1. Restricted/Declarable Substances:

Table 1 identifies substances and categories of substances that are restricted and/or declarable. Suppliers shall identify via the DF, any substance/category of substance listed in Table 1, present in supplied product including CAS and concentration (% wt/wt).

**Table 1 - Restricted/Declarable Substances and Categories of Substances in Articles**

|  |  |  |
| --- | --- | --- |
| **SUBSTANCE / CATEGORY** | **REPORTABLE APPLICATION** | **THRESHOLD LEVEL** |
| **Known, Probable or Suspected Carcinogens, Mutagens and Reproductive Toxicants:**Materials that areincluded on the following regulatory lists:1. Known human carcinogens:a. IARC 1; b. ACGIH A1; c. NTP “known to be human carcinogen” 2. Suspected to be carcinogens:a. IARC 2A; b. ACGIH A2; c. NTP “reasonably anticipated to be a carcinogen” 3. 13 OSHA carcinogens 4. Carcinogen, Mutagen, Reproductive Toxicant (CMR): a. GHS category 1A, 1B & 2; 5. CERHR classification "Serious concern" and "Concern" for adverse reproductive effects6. California Proposition 65 list of reproductive/ developmental toxicants and carcinogens (in consideration with other agency lists, not as a sole determinant) 7. The Toxic Substances Control Act (TSCA):Chemicals of Concern categories | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Other Health Concerns**: Materials that are known to cause irreversible significant adverse effects in humans or are strongly presumed to have the potential to cause such effects by relevant routes of exposure (other than carcinogens, mutagens and reproductive toxicants), which are listed below:1. TSCA Chemicals of Concern2. GHS criteria: Specific Target Organ Toxicity (STOT) category 1 & 23. Endocrine disruptors4. Sensitizer i.e. skin or respiratory e.g. Acrylate monomers, acrylate laminations or overcoats, products containing cross-linkers, hardeners, or preservatives 5. Silver and Silver compounds6. Nanomaterials |  | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Environmental Concerns**: Materials that meet the criteria as defined by regulatory authorities e.g. ECHA, USEPA, etc. as:1. Persistent, bioaccumulative, and toxic (PBT)
2. Very persistent and very bioaccumulative (vPvB)
3. Persistent organic pollutants (POPs)
4. Ozone depleting substance (ODS)
5. Materials with high aquatic toxicity, i.e., acute LC/EC50 values ≤ 1 mg/L, to the environment
6. Intentionally added microplastics
7. Polyvinyl Chloride (PVC) Polyvinylidene dichloride (PVDC)
 | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Sensitizers**: Materials that are classified as sensitizers i.e. respiratory or skin | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **TSCA:**Substances restricted/prohibited under [TSCA section 6 (40 CFR 751](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-751)) including, but not limited to:1. PIP 3:1 phenol, isopropylated phosphate (3:1), CAS 68937-41-7
2. DecaBDE decabromodiphenyl ether, CAS 1163-19-5
3. 2,4,6 TTBP  2,4,6-tris(tert-butyl)phenol, CAS 732-26-3
4. HCBD hexachlorobutadiene, CAS 87-68-3
5. PCTP pentachlorothiophenol, CAS 133-49-3
 | All | PIP 3:1, DecaBDE, and HCBD prohibited at any amount.PCTP – 1% wt/wt (100 ppm)2,4,6 TTBP – 0.3% wt/wt (3000 ppm) |
| **Swiss Chemical Risk Reduction Ordinance (ORRCHem) List:** Any substance covered by this piece of legislation. For further information see [Swiss Chemical Risk Reduction Ordinance (ORRChem) List](https://www.chemsafetypro.com/Topics/CH/Siwss_Chemical_Risk_Reduction_Ordinance_ORRChem.html) or [Federal Office of Public Health (FOPH)](https://www.fedlex.admin.ch/eli/cc/2005/478/en) | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| EU REACH and global equivalents:Substances Restricted under ANNEX XVII or subject to Authorisation under Annex XIV of REACH Regulation (EC) No 1907/2006. For global EU REACH equivalents, please see <https://www.chemsafetypro.com/Topics/Category/REACH_and_Chemical_Control_Laws.html> | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| Any per- and polyfluoroalkyl substances i.e. any Substances that contain at least one aliphatic -CF2- or -CF3- element, including but limited to:1. Per- and polyfluoroalkyl substances (PFAS)
2. perfluorooctane sulfonic acid and its derivatives (PFOS)
3. perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
4. Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds
5. perfluorinated carboxylic acids (C9-14 PFCAs) including their salts and precursors
6. perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances
7. undecafluorohexanoic acid (PFHxA), its salts and related substances.
 | Any substance listed here:<https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas> | Intentionally Added or Known to be present as an impurityUse in manufacturing |
| **Any substance that is banned, restricted or requires authorisation** e.g. covered by anotherInternational Chemical Convention | Any substance listed here: <https://www.chemsafetypro.com/Topics/Category/Substance_of_Concern_and_Restriction.html> |  |
| Biocides:Suppliers are required to identify biocides (i.e. active substances/biocidal products) contained in Articles and upon request, provide information and other assistance to Kodak Alaris to meet regulatory requirements in countries with biocidal or related requirements. Countries having established biocide directives include, but are not limited to Canada (PCA), European Union (Biocide Products Directive) and US (FIFRA). Do any items contain biocides (i.e. active substances or biocidal products)? (if yes, provide CAS# and % w/w) |  |  |
| SVHCSuppliers are required to declare Substances of Very High Concern (SVHC) present at greater than 0.1% by weight. SVHC are identified on the “Candidate List” in Annex XIV of the European Chemical Agency Article 59(1) of the Regulation (EC) No. 1907/2006 (European Union REACH).  | **The SVHC list is found at:** <https://echa.europa.eu/candidate-list-table> on the European Chemical Agency website. | Known to be Present above 0.1% wt/wt (1000 ppm) |
| Proposition 65Suppliers shall declare when labeling is required in the state of California, per the California State Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). | *The Proposition 65 list includes lead, mercury and DEHP, and can be found at* [*http://www.oehha.ca.gov/prop65/prop65\_list/Newlist.html#list*](http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html#list) | As per Proposition 65 list |
| **Conflict Minerals**Suppliers are required to declare the presence of Conflict minerals (tantalum, tin, tungsten, gold, and their derivatives). | All | Any quantity |

* 1. Chemical Inventories and Notifications

Suppliers via the DF must identify any global Chemical Inventories and Notification requirements that are NOT met e.g. Australian Inventory of Industrial Chemicals (AIIC), TSCA (US), EU Classification, Labeling and Packaging (CLP) Annex VIII Poison Centre Notification (PCN), etc. For a list of current Global Chemical Inventories and Notifications: <https://www.chemsafetypro.com/Topics/Category/Global_Chemical_Inventories.html>

* 1. **Releases or emissions from Articles during Foreseeable Use:**

Suppliers must identify any release or emission from the product during normal or reasonably foreseeable conditions of use (e.g., volatile organic compounds, carbon black, ozone, styrene, objectionable odors, dust). If requested by Kodak Alaris, Supplier shall provide copies of emissions testing or additional air emissions data.

* 1. **Paper and Printed Materials:** Pulp and paper products shall be sourced from legally harvested forests. Suppliers shall have a process for determining the origin of all pulp and paper products and make this information available to Kodak Alaris upon request. Articles subject to the regulation on deforestation-free products (EU 2023/1115) should include applicable due diligence declaration related to the source.
	2. **Product Safety (PS):**

***Articles*** shall conform to all applicable Product Safety (PS) standards appropriate for intended markets identified in the Product Requirements Document (PRD) or equivalent. Upon request, certificates, test reports and supporting documentation shall be provided.

1. [Chemical Products (Substances or Mixtures) Requirements](#Chemical)

The Supplier shall evaluate **Chemical Products** to ensure the following EHS product Specifications are met.

* 1. **Safety Data Sheets (SDS):**

Suppliers are required to attach an SDS for chemical products (substances or mixtures) to the completed Supplier Declaration Form. The SDS shall comply with applicable provisions of the OSHA Hazard Communication Standard 1910.1200, GHS (Globally Harmonized System) of Classification and Labeling of Chemicals, or the comparable regulation for the country where the material is transported. The SDS shall be provided in US English and EU English as a minimum and other countries as requested by Kodak Alaris.

* 1. **Restricted/Declarable Substances:**

Table 2 identifies substances and categories of substances that are restricted and/or declarable. Suppliers shall identify via the DF, any substance/category of substance listed in Table 1, present in supplied product including CAS and concentration (% wt/wt).

**Table 2 - Restricted/Declarable Substances and Categories of Substances in Chemical Products**

|  |  |  |
| --- | --- | --- |
| **SUBSTANCE / CATEGORY** | **REPORTABLE APPLICATION** | **THRESHOLD LEVEL** |
| **Known, Probable or Suspected Carcinogens, Mutagens and Reproductive Toxicants:**Materials that areincluded on the following regulatory lists:1. Known human carcinogens:a. IARC 1; b. ACGIH A1; c. NTP “known to be human carcinogen” 2. Suspected to be carcinogens:a. IARC 2A; b. ACGIH A2; c. NTP “reasonably anticipated to be a carcinogen” 3. 13 OSHA carcinogens 4. Carcinogen, Mutagen, Reproductive Toxicant (CMR): a. GHS category 1A, 1B & 2; 5. CERHR classification "Serious concern" and "Concern" for adverse reproductive effects6. CA Proposition 65 list of reproductive/developmental toxicants and carcinogens (in consideration with other agency lists, not as a sole determinant) 7. TSCA Chemicals of Concern categories | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Other Health Concerns**: Materials that are known to cause irreversible significant adverse effects in humans or are strongly presumed to have the potential to cause such effects by relevant routes of exposure (other than carcinogens, mutagens and reproductive toxicants), which are listed below:1. TSCA Chemicals of Concern2. GHS criteria: Specific Target Organ Toxicity (STOT) category 1 and 23. Endocrine disruptors4. Sensitizer i.e. skin or respiratory e.g. Acrylate monomers, acrylate laminations or overcoats, products containing cross-linkers, hardeners, or preservatives 5. Silver and Silver compounds6. Nanomaterials |   | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Environmental Concerns**: Materials that meet the criteria as defined by regulatory authorities e.g. ECHA, USEPA, etc. as:1. Persistent, bioaccumulative, and toxic (PBT)
2. Very persistent and very bioaccumulative (vPvB)
3. Persistent organic pollutants (POPs)
4. Ozone depleting substance (ODS)
5. Materials with high aquatic toxicity, i.e., acute LC/EC50 values ≤ 1 mg/L, to the environment
6. Intentionally added microplastics
7. Polyvinyl Chloride (PVC) Polyvinylidene dichloride (PVDC)
 | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Sensitizers**: Materials that are classified as sensitizers i.e. respiratory or skin | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| **Swiss Chemical Risk Reduction Ordinance (ORRCHem) List:** Any substance covered by this piece of legislation. For further information see [Swiss Chemical Risk Reduction Ordinance (ORRChem) List](https://www.chemsafetypro.com/Topics/CH/Siwss_Chemical_Risk_Reduction_Ordinance_ORRChem.html) or [Federal Office of Public Health (FOPH)](https://www.fedlex.admin.ch/eli/cc/2005/478/en) | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| EU REACH and global equivalents:Substances Restricted under ANNEX XVII or subject to Authorisation under Annex XIV of REACH Regulation (EC) No 1907/2006. For global EU REACH equivalents, please see <https://www.chemsafetypro.com/Topics/Category/REACH_and_Chemical_Control_Laws.html>  | All | Intentionally Added or Known to be Present above 0.1% wt/wt (1000 ppm) |
| Any per- and polyfluoroalkyl substances i.e. any Substances that contain at least one aliphatic -CF2- or -CF3- element, including but limited to:1. Per- and polyfluoroalkyl substances (PFAS)
2. perfluorooctane sulfonic acid and its derivatives (PFOS)
3. perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
4. Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds
5. perfluorinated carboxylic acids (C9-14 PFCAs) including their salts and precursors
6. perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances
7. undecafluorohexanoic acid (PFHxA), its salts and related substances.
 | All | Intentionally Added or Known to be present as an impurityUse in manufacturing |
| **Any substance that is banned, restricted or requires authorisation e.g. covered by another** International Chemical Convention | Any substance listed here: <https://www.chemsafetypro.com/Topics/Category/Substance_of_Concern_and_Restriction.html> |  |
| Biocides:Suppliers are required to identify biocides (i.e. active substances/biocidal products) contained in Articles and upon request, provide information and other assistance to Kodak Alaris to meet regulatory requirements in countries with biocidal or related requirements. Countries having established biocide directives include, but are not limited to Canada (PCA), European Union (Biocide Products Directive) and US (FIFRA). Do any items contain biocides (i.e. active substances or biocidal products)? (if yes, provide CAS# and % w/w) |  |  |
| SVHCSuppliers are required to declare SVHC (Substances of Very High Concern) present at greater than 0.1% wt/wt. SVHC are identified on the “Candidate List” in Annex XIV of the European Chemical Agency Article 59(1) of the Regulation (EC) No. 1907/2006 (European Union REACH).  | The SVHC list is found at: <https://echa.europa.eu/candidate-list-table> on the European Chemical Agency website.  | Known to be Present above 0.1% wt/wt (1000 ppm) |
| Proposition 65Suppliers shall declare when labeling is required in the state of California, per the California State Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). | The Proposition 65 list includes lead, mercury and DEHP, and can be found at <http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html#list> | As per Proposition 65 list |
| **Conflict Minerals**Suppliers are required to declare the presence of Conflict minerals (tantalum, tin, tungsten, gold, and their derivatives). | All | Any quantity |

* 1. **Chemical Inventories and Notifications:**

Suppliers via the DF must identify any global Chemical Inventories and Notification requirements that are NOT met e.g. AIIC (Australia), TSCA (US), EU CLP Annex VIII PCN, etc. For a list of current Global Chemical Inventories and Notifications: <https://www.chemsafetypro.com/Topics/Category/Global_Chemical_Inventories.html>

* 1. **"Only Representatives" or equivalents:**

 Suppliers via the DF must notify whether they agree to include Kodak Alaris volumes/use as pertaining to any global REACH Regulations.

* 1. **Emissions from Products:**

Suppliers must identify any release or emission from the product during normal or reasonably foreseeable conditions of use (e.g., volatile organic compounds, carbon black, ozone, styrene, objectionable odors, dust). If requested by Kodak Alaris, Supplier shall provide copies of emissions testing or additional air emissions data.

1. [Packaging Requirements](#Packaging)

The Supplier shall evaluate ***Packaging Materials*** to ensure the following EHS Product Specifications are met.

* 1. **Packaging Bill of Materials (BoM):**

The Supplier shall provide a[**Bill of Materials**](https://www.kodakalaris.com/getmedia/2962294f-f87f-4271-9034-342b06e5973e/Kodak-Alaris-BOM-Template-Blank-2021_1.xlsx.aspx) (BoM) for all packaging supplied to Kodak Alaris. Supplier shall indicate the presence and percentage of recycled content.

* 1. **Restricted Materials:**

Table 3 identifies substances and categories of substances that are restricted. Suppliers shall identify via the DF, any substance/category of substance listed in Table 3, present in supplied product packaging including CAS and concentration (% wt/wt).

Table 3 - Restricted Substances and categories of substances in Packaging

|  |  |  |
| --- | --- | --- |
| **SUBSTANCE / CATEGORY** | **REPORTABLE APPLICATION** | **THRESHOLD LEVEL** |
| Dimethyl fumarate | All | 0.00001% wt/wt (0.1 ppm) of the packaging item |
| Heavy Metals:Cadmium/Cadmium Compounds Hexavalent Chromium/Hexavalent Chromium Compounds (Cr+6)Lead/Lead CompoundsMercury/Mercury Compounds | Package or individual packaging component | Intentionally added The total concentration of these heavy metals cannot exceed 0.01% wt/wt (100 ppm).  |
| Formaldehyde | Textiles | 0.0075% wt/wt (75 ppm) of textile item |
| Methyl bromide | Fumigation of wood pallets in EU | Intentionally added |
| Ozone Depleting Substances | All | Intentionally added Use in manufacturing |
| Polyvinyl Chloride (PVC) and Polyvinylidene dichloride (PVDC) | All | Intentionally added |

[EU Directive 2018/852 on packaging and packaging waste](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018L0852&from=EN)

* 1. **Substances of Very High Concern (SVHC)**

Suppliers are required to declare SVHC (Substances of Very High Concern) present at greater than 0.1% wt/wt. SVHC are identified on the “Candidate List” in Annex XIV of the European Chemical Agency Article 59(1) of the Regulation (EC) No. 1907/2006 (European Union REACH).

* 1. **Separability:**

Suppliers shall ensure that packaging components are readily separable for recycling.

* 1. **Packaging labeling:**

Suppliers shall ensure that packaging components are labeled to indicate material type/composition in accordance with applicable regulations (e.g., 97/129/EC)

* 1. **Plastic Packaging:**

Apart from exempted packaging, all plastic packaging materials must be marked with the appropriate Society of the Plastics Industry Inc. (SPI) resin identification code.

* 1. **Paper Packaging:**

Pulp and paper products shall be sourced from legally harvested forests. Suppliers shall have a process for determining the origin of all pulp and paper products and make this information available to Kodak Alaris upon request.

Recycled content targets:

* Paperboard – 80%
* Corrugated fiberboard – 25%
* Solid fiberboard – 40%
* Spiral-wound tubes – 90%

Additionally, elemental chlorine shall not be used to bleach virgin or recovered content fibers used in product packaging.

* 1. **Wood Packaging:**

Solid wood packaging used in international trade and may serve as a pathway for plant pests shall be treated and marked when exported or imported and be free of bark, according to UN Standard ISPM-15. For further information refer to [**Appendix C**](#Appendix_H).

Sawdust, wood wool, shavings and raw wood cut into thin pieces are not suitable pathways for introduction of quarantine pests and are not regulated unless technically justified.

* 1. **Regional Requirements for Product Packaging:**

***Packaging*** must comply with various state, country and regional requirements as outlined below. Additional information on these requirements can be obtained from references contained in [**Appendix C**](#Appendix_H). More specific requirements driven by the product market will be defined in the Product Requirements Document.

* + 1. **Regional Packaging Fees:** Suppliers will be asked to provide the weight, volume, and material composition of all ***Packaging*** supplied to Kodak Alaris in order to facilitate calculation of Regional Packaging Fees.

## Requirements in the European Union (EU):

## Article 9 of the European Parliament and Council Directive EU 2018/852 on packaging and packaging waste

In addition to satisfying the “essential requirements” in this Directive, the Directive also includes a "conformity assessment procedure" which requires the manufacturers to "certify that their packaging complies with the requirements of the packaging and packaging waste directive." Unless ***Packaging*** design is specified by Kodak Alaris, Suppliers of packaged products shall be able to produce the Conformity Assessment Report when requested.

## Manual Handling

## EU Council Directive 90/269/EEC requires that manually handled packages, where there is a risk of back injury to workers, be marked with the weight of the load and the center of gravity when a package is asymmetrically loaded.

## The maximum package weight for products, which are expected to be handled manually, should not be greater than 29 lbs. (13 kg). Any package weighing more than 40 lbs. (19 kg) should consider adding additional design features, such as handles or handle holes, to aid in the manual handling of that case. Any package weighing more than 51 lbs. (23 kg) should be transported on a pallet or some other mechanical means of movement.

## Dimethylfumarate

## According to European Commission Decision 2009/251/EC, dimethylfumarate (CAS No. 624-49-7) cannot be present in Packaging at a concentration greater than 0.1 mg/kg. Because this substance is most commonly used in desiccants, Suppliers of these packaging components are required to provide an EU compliant Material Safety Data Sheet and an analytical test report for dimethylfumarate content from a laboratory accredited to ISO/IEC 17025 or an equivalent standard in order to demonstrate that this requirement has been met.

* + 1. **Requirements in US&C:** In the US, packaging requirements vary at the state level. Generally, the sum of the concentration levels of lead, cadmium, mercury, or hexavalent chromium shall not exceed 0.01% wt/wt (100 ppm) as specified in Table 3 above.
		2. **Requirements in China:** All external packaging for electronic and electrical equipment covered under China’s *Management Methods for Controlling Pollution Caused by Electronic Information Products (China RoHS) shall be lab*eled as required by China’s National Standard for Packaging Recycling Marks GB 18455-2001 and SJ/T 11364-2014.
		3. **Requirements in South Korea:** Article 14 of the “Act on the Promotion of Saving and Recycling Resources” requires that all foam packaging components used as cushioning materials for electronic equipment in South Korea be marked with a "separate discharge" mark. The mark facilitates the separation of products and packaging for recycling. Exemptions include packaging and packaging component materials with a surface area of 50 cm2 or less; containers with components weighing 30 grams or less; and packaging and packaging component materials whose nature and structure impede printing, engraving, or labeling on the material.
		4. **Requirements in Australia:** Kodak Alaris is a signatory to the Australian Packaging Covenant Organisation (APCO). We require our suppliers to review the Key Performance Indicator (KPI 1) of the APCO Sustainable Packaging Guidelines (SPGs). Links to the APCO website and SPGs are provided in [Appendix C](#_Appendix_C_–).

1. [Appendices](#Appendix)

## [Appendix A – Safety Traceability Requirements for Critical Components](#Appendix_F)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description** | **Plastic & Foam** | **Wire Harness** | **Circuit Boards** | **Safety Label** |
| **Requirements** | Materials shall be identifiable to safety agency inspectors. | Shall be identifiable as having been produced under the UL Recognized Wire Harness Manufacturer’s Program and CSA Certified Wire Harness Program. | Shall be identifiable as having been produced under the UL Recognized Component Printed Wiring Program. | Shall be identifiable as having been produced under the UL and CSA Marking and Labeling System approval programs. |
| **Required Information from supplier with each shipment** | 1. Molder name2. Kodak Alaris part number3. Raw material manufacturer name4. Plastic manufacturer type designation (e.g.,"Cycoloy C6200")5. Month and year molded6. UL Recognized Molder program number, if applicableIn addition, for parts with metallic (EMI) coating, identify the applicator, the process used, and the metallic (EMI) coating material used. | Wire Harness label on the shipping container or on each harness | Mark parts according to UL Printed Wiring Program (e.g. Manufacturer’s name or trademark and board type.) | Manufacturer’s identity (e.g., name or trademark) and manufacturer’s label type (e.g. Type 123). |
| **Acceptable methods to provide traceability to Kodak Alaris** | ·Molded on each part or·"Stuffer sheet" containing the 6 items above in the smallest shipping container or·Label on every shipping container stating the 6 items above. | ·Label on each harness·Label the smallest deliverable package.·Label the shipping box for the harnesses contained in the box. | Mark parts according to UL Printed Wiring Program requirements. | ·For CSA approved labels, place identifier on each label.·For UL approved labels, place the identifier on each label or smallest delivered package. |
| **Related supplier safety expectations** | Parts will be produced under the UL Recognized Fabricated Parts Program. | Harnesses will be produced under the UL Recognized Wiring Harness Manufacturer program and be CSA Certified. | Parts will be produced under the UL Recognized Printed Wiring Board program. | Safety labels will be approved to UL/CSA "Marking and Labeling System" requirements. |

## [Appendix B – Product Safety and EMC References](#Appendix_G)

The table below includes references to international regulations and standards regarding Product Safety and Electromagnetic Compatibility (EMC). This is not a complete list of requirements. It is provided to indicate some common regulatory requirements impacting Kodak Alaris products. The Product Requirements Document (PRD) for specific products may contain additional requirements. Suppliers are expected to meet all equipment regulatory requirements for the specified markets on which the equipment will be placed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Market** | **Regulation/Standard** | **Title** | **Type** |
| International CB Scheme | IEC 62368-1 | Safety of Information Technology Equipment | Safety |
| EU/EEA | [2014/35/EU](http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/low-voltage/) | Low Voltage Directive | Safety |
| EU/EEA | EN 62368-1 | Safety of Information Technology Equipment | Safety |
| EU/EEA | EN 62471 | Photobiological Safety of Lamps and Lamp Systems | Safety |
| EU/EEA | EN 60825-1 | Safety of laser products | Safety |
| Canada  | CSA 22.2 No. EN 62368-1 | Safety – Information Technology Equipment | Safety  |
| Russia | Eurasian Low Voltage Directive | Technical requirement similar to EU, requires EAC Certifications | Safety |
| EU/EEA | EN 55032 | Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement | EMC |
| EU/EEA | EN 55035 | Information technology equipment. Immunity characteristics. Limits and methods of measurement | EMC |
| United States | [FCC CFR 47 Part 15](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title47/47cfr15_main_02.tpl) | Telecommunications – Radio Frequency Device – Intentional, Unintentional and Incidental Radiators | EMC |
| Canada | [ICES-003](http://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf00020.html) | ITE – Limits and Measurement Methods | EMC  |
| Korea | KS C 9832 (CISPR 32) | EU standards tested at Korean line voltage and frequency | EMC |
| Korea | KS C 9835 (CISPR 35) | EU standards tested at Korean line voltage and frequency | EMC |
| Australia | Radio Communications Act 1992 | Compliance with EU standards and Australian RMC marking requirements | EMC |
| Russia | Eurasian EMC Directive | Technical requirement similar to EU, requires EAC Certifications | EMC |

## [Appendix C – Packaging References](#Appendix_C)

# [EU Directive 2018/852 on packaging and packaging waste](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018L0852&from=EN) (amended *Directive 94/62/EC on Packaging and Packaging Waste;* full history of amendments can be found [here](http://europa.eu/legislation_summaries/environment/waste_management/l21207_en.htm)).

**Plastic Packaging Materials**

Further Information on the SPI resin identification code can be obtained at: <https://plastics.americanchemistry.com/Plastic-Resin-Codes-PDF/>

**Wood Packaging Materials**

Approved treatment includes fumigation with methyl bromide or heat treatment (HT)—heated to a core temperature of 56 deg C (133 deg F) for 30 min. Kiln drying (KD) or chemical pressure impregnation (CPI) may be considered heat treatment to the extent that these meet the heat treatment specifications mentioned.

Treated solid wood packaging materials shall be marked with the International Plant Protection Convention (IPPC) logo, the ISO two-letter country code followed by a unique number assigned by the National Plant Protection Organization (NPPO) to the producer, and the IPPC approved abbreviation for the phytosanitary treatment measure used (e.g., HT and MB).

Recycled, remanufactured, or repaired wood packaging material should be re-certified and re-marked. All components of such material should have been treated.

Further information may be obtained at <https://www.ippc.int/>.

**European Council Directive 90/269/EEC on Manual Handling Requirements**

Further information can be found at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0269:20070627:EN:PDF>

**Korean Separate Discharge Mark**

Further information can be found at: <http://www.keco.or.kr/kr/business/resource/contentsid/1564/index.do>

**Australian Packaging Covenant Organisation -** [Sustainable Packaging Guidelines](https://apco.org.au/sustainable-packaging-guidelines)

There are 4 key Principles our suppliers should consider in the design or procurement of packaging that Kodak Alaris will place on the market in Australia, to improve its sustainability. Further information may be found at <https://apco.org.au/>

1. **Fit-for purpose:** Packaging should be designed to meet market and consumer needs, while minimising net impact in a cost-effective way.
2. **Resource efficiency:** Packaging should be designed to minimise the use of materials and other resources without compromising product quality and safety.
3. **Low-impact materials:** Packaging should be designed to minimise the environmental and social impact of materials and components. Materials should be selected on science and incorporate a whole-of-lifecycle approach.
4. **Resource recovery:** Packaging should be designed to maximise its potential for recovery and recycling, and to minimise the environmental and social impacts of its disposal.

Each principle has several potential strategies our suppliers should review:

**a) Meet technical performance requirements**: Minimise supply chain cost, meet consumer needs and expectations, including for accessibility.

**b) Minimise materials**: Use recycled materials, minimise transport impacts, maximise water and energy efficiency.

**c) Minimise risks associated with potentially toxic and hazardous materials**: Use renewable or recyclable materials, Use materials from responsible suppliers.

**d) Design for reuse where appropriate**: Design for recovery, Design for litter reduction, Inform consumers about appropriate disposal.

## [Appendix D – Revision History](#Appendix_I)

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Section | ***Change*** | Date |
| 5 | All | Reorganization and update  | October 2024 |
| 4 | All | Reorganization and update | May 2021 |
| 3 | 8 | Addition of APCO Requirements in Appendix H | Feb 26, 2018 |
| 2 | All | General update of links and references | Aug. 17, 2017  |
| 1 | All | Release of Kodak Alaris EHS Product Specification Document (Ver. 1.0) | Dec. 1, 2014 |

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