

Restricted Substances List - Packaging (RSL-P)

Scope of the Restricted Substances List

This RSL is applicable for all primary packaging supplied to Ontex. By primary packaging we mean packaging conceived to constitute a sales unit to the final user or consumer at the point of purchase.

Purpose of the Restricted Substances List

As a manufacturer of hygiene products, Ontex considers quality and product safety its key priorities. All raw materials are selected carefully in accordance with all applicable regulations on product safety. Furthermore, we want our products to be compliant with various other legal obligations, official recommendations, codes of practice, voluntary commitments, and state of the art toxicological considerations.

Ontex has defined a list of substances of concern to guarantee product safety and protect employees and consumers from exposure to potential health hazards.

The supplier must inform Ontex of all changes which may impact regulatory and safety compliance. This document is not intended to replace the Ontex Conformity Declaration, which represents the engagement of the supplier to comply with regulatory and safety requirements mentioned in that specific document.

This Restricted Substances List does not replace legal requirements applicable for chemicals globally, such as:

- European Union Regulation for registration, evaluation, authorisation and restriction of chemicals (REACH) and corresponding legislation for outside the EU (European Union)
- European CLP 1272/2008 regulation
- US California Proposition 65
- 94/62/EC on Packaging and Packaging Waste Directive
- CONEG Model Toxics in Packaging legislations European
- Material in contact with food legislation (21 CFR 175, 176, 177, 178, 181, 182, 184, 186)
- EUPIA and indirect food additives 21CFR 178.3297 for inks
- FDA 21cfr175.105 for adhesive
- LFGB: the umbrella law of the German food law system, German Federal Register ("Bundesgesetzblatt")
- ...

However, every supplier should be aware of and adhere to Ontex's requirements. If for a technical unavoidable reason this list cannot be respected, Ontex should be informed as quickly as possible to enable an exposure-based safety evaluation. Legal obligations need to be respected without exception.

Specific case of mechanical post-consumer recycled packaging (MPCR)

Looking at the uncertainties of any potential presence of contaminants in MPCR packaging and to ensure safety to our consumers and employees, substances marked with a red star* need to be monitored by the supplier for each batch delivered to Ontex. Ontex can request a Certificate of Analysis (COA, quantification/extractable method) for MPCR packaging at any time.

Ontex considers that it is the supplier's responsibility to ensure safety of the material delivered to us and testing of hazardous substances is required.

Supplier name:

Supplier signature:

Date:

List of prohibited or restricted substances

These substances cannot be added intentionally into primary packaging sold to Ontex.
Non-intentionally added substances (NIAS) should be monitored and cannot exceed the NIAS value mentioned (when available).
In the case of "restricted" status, the restriction in the status column will apply.

Category/Substances	Comments
Carcinogenic, mutagenic, reprotoxic (CMR) substances, Cat 1A, 1B and 2 according to CLP Regulation (Note: this covers hazard statements H340, H350, H360, H362 or risk phrases R45, R46, R49, R60, R61, R64 according to Directive 67/548/EEC)	PROHIBITED
Endocrine disruptor as defined in following list (List I,II and III) https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu	PROHIBITED
1,4 Dioxane*	PROHIBITED NIAS <10 mg/kg TEST MANDATORY FOR MPCR PACKAGING
Alkylphenol and alkylphenol ethoxylated*	PROHIBITED NIAS: Nonylphenol-di-ethoxylate, octylphenol, TNPP, nonylphenol, ... < 5 mg/kg TEST MANDATORY FOR MPCR PACKAGING
Azodyes (Entry.43 REACH)*	PROHIBITED TEST MANDATORY FOR MPCR PACKAGING
Benzophenones	PROHIBITED
Butylated hydroxyanisole (BHA)	PROHIBITED
Bisphenol*	PROHIBITED NIAS: Bisphenol A < 0.01% TEST MANDATORY FOR MPCR PACKAGING
Chlorinated hydrocarbons (Entry.34,35, 36,37, 38 REACH)	PROHIBITED
<u>Coating in direct contact with finished product restriction</u> - In compliance with US-FDA CFR 175,176, 177,178 - In compliance with BfR recommendations for material in contact with food	RESTRICTED
Dioxins/furans/PCB*	PROHIBITED NIAS: summed of dibenzo-p-dioxins (PCDDs), dibenzofurans (PCDFs) and non-ortho/mono-ortho PCB < 2 ng/kg (Sum TEQ- WHO 2005) TEST MANDATORY FOR MPCR PACKAGING
Elemental chlorine bleaching	PROHIBITED Only ECF or TCF bleaching accepted AOX (adsorbable organic halogens) < 5 mg/kg
Flame retardants	PROHIBITED
Formaldehyde* and formaldehyde releaser (bronopol, quaternium-15, DMDM hydantoin, imidiazolidinyl urea, diazolidinyl urea, glyoxal, ...)	PROHIBITED NIAS < 0.5 mg/kg TEST MANDATORY FOR MPCR PACKAGING
Genetically modified organism (GMO)	PROHIBITED
Glyphosate/AMPA* (for natural fibres based packaging e.g., cardboard, paperboard)	PROHIBITED NIAS < 0.5 mg/kg TEST MANDATORY FOR MPCR PACKAGING
Heavy metals* In accordance with CONEG and 94/62/EC packaging and packaging waste directive	PROHIBITED NIAS: Oekotex Standard 100, Annex 6, class1 requirement TEST MANDATORY FOR MPCR PACKAGING
<u>INKS restriction:</u> - Mineral oil quality MOSH < 0,1% / MOAH < 0,1 % - In accordance with EUPIA list - In accordance with 2 CFR 178.3297 - Metallic ink prohibited for French market	RESTRICTED

Category/Substances	Comments
Microplastic	PROHIBITED
Nanomaterials as defined by EC recommendations 2011/696/EU Last version (June 2022) can be found on this link SWD_2022_150_2_EN_part1_v4.pdf(europa.eu)	PROHIBITED
Organotin compounds*	PROHIBITED NIAS: TBT (Tributyltin): < 2 µg/kg Dibutyltin (DBT), triphenyltin (TPT), monobutyltin (MBT), mono-octyltin (MOT), dioctyltin (DOT) < 10 µg/kg TEST MANDATORY FOR MPCR PACKAGING
Pentachlorophenol (PCP)	PROHIBITED
Per and polyfluoroalkyl substances (PFAS) included perfluorooctane sulfonates (PFOS) and PFOS precursor*	PROHIBITED TEST MANDATORY FOR MPCR PACKAGING
Phthalates*	PROHIBITED NIAS: < 0.01% TEST MANDATORY FOR MPCR PACKAGING
Polyaromatic hydrocarbon (PAH)*	PROHIBITED NIAS: sum of 16 PAH according to EPA-list: < 0.2 mg/kg In case of any known PAH > 0.2 mg/kg TEST MANDATORY FOR MPCR PACKAGING
Polybromated substances (Entry.8 REACH)	PROHIBITED
Polychloroterphenyl and biphenyl (PCT/PCB) (Entry.1 REACH)	PROHIBITED
Polyvinyl chloride (PVC)	PROHIBITED
Polystyrene or expanded	PROHIBITED
Titanium dioxide	RESTRICTED Not in nano form, not in free powder

* Need to be tested for MPCR packaging. A COA can be requested at any time.