

Restricted Substances List (RSL)

Scope of the Restricted Substances List

This RSL is applicable for all materials supplied to Ontex to produce absorbent hygienic products (babycare, external and internal feminine hygiene, incontinence products) but also absorbent hygienic finished products and other personal care finished products manufactured by a third party for Ontex. Packaging is excluded from this RSL and is treated separately.

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 (Classification, Labelling and Packaging) 1272/2008 regulation
- US (United States) California Proposition 65
- European Biocidal Regulation
- EUPIA for inks
- IFRA for perfume
- (EC) 1223/2009 Cosmetic regulation
- FDA (Food and Drug Administration) 21cfr175.105 for adhesive
- Material in contact with food legislation
- ...

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.

Supplier name :

Supplier signature :

Date :

List of prohibited or restricted substances

These substances cannot be added intentionally into material 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	Status
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
Acrylic acid monomer content in super absorbent polymer	RESTRICTED Only as monomer residual content < 300 mg/kg
Alkylphenol and alkylphenol ethoxylated	PROHIBITED NIAS: Nonylphenol-di-ethoxylate and Nonylphenol < 5 mg/kg
Allergens as defined by Regulation (EC) 1223/2009	PROHIBITED
Azodyes (Entry.43 REACH)	PROHIBITED
Benzophenones	PROHIBITED
Butylated hydroxyl anisole (BHA)	PROHIBITED
Bisphenol	PROHIBITED NIAS: Bisphenol A < 0.01%
Chlorinated hydrocarbons (Entry.34,35, 36,37, 38 REACH)	PROHIBITED
Colophonium/natural rosin	PROHIBITED
Dimethylacetamide (DMAC)	PROHIBITED NIAS: DMAC < 0.1 mg/kg for elastic based material only
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)
Elemental chlorine bleaching	PROHIBITED Only ECF or TCF bleaching accepted AOX (Adsorbable Organic Halogens) < 5 mg/kg
Fibre finish from non-woven or natural fibres (hydrophilic treatment)	RESTRICTED Should meet material in direct contact with food requirement
Flame retardants	PROHIBITED
Formaldehyde and formaldehyde releaser (bronopol, quaternium-15, DMDM hydantoin, imidazolidinyl urea, diazolidinyl urea, glyoxal, ...)	PROHIBITED NIAS < 0.5 mg/kg
Genetically modified organism (GMO)	PROHIBITED

Category/Substances	Status
Glyphosate/AMPA	PROHIBITED NIAS < 0.5 mg/kg
Heavy metals	PROHIBITED NIAS: Oekotex Standard 100, Annex 6, class1 requirement
Iodopropynyl butylcabamate (IPBC)	PROHIBITED
Isobutylparaben/isopropyl paraben	PROHIBITED
Isocyanates	PROHIBITED
Isothiazolinones	PROHIBITED (Material with direct skin contact) RESTRICTED (Material with no direct skin contact or rinseable < 15 ppm for MIT and CMIT/MIT only)
Lillial (butylphenyl methylpropional)	PROHIBITED
Microbeads	PROHIBITED
Musk, nitro musk, polycyclic musk	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
Natural rubber/natural rubber latex	PROHIBITED
Octomethylcyclotetrasiloxane (D4)	PROHIBITED NIAS < 0.01%
Organotin compounds	PROHIBITED NIAS: TBT (Tributyltin): < 2 µg/kg Dibutyltin (DBT), triphenyltin (TPT), monobutyltin (MBT), mono-octyltin (MOT), dioctyltin (DOT) < 10 µg/kg
Pentachlorophenol (PCP)	PROHIBITED
Per and polyfluoroalkyl substances (PFAS) including Perfluorooctane sulfonates (PFOS) and PFOS precursors	PROHIBITED
Phenoxyethanol	RESTRICTED for cosmetic product dedicated for baby < 0.4% PROHIBITED for cosmetic product dedicated for baby nappies
Phthalates	PROHIBITED NIAS: < 0.01%
Polyaminopropyl biguanide	PROHIBITED
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
Polybromated substances (Entry.8 REACH)	PROHIBITED
Polychloroterphenyl and biphenyl (PCT/PCB) (Entry.1 REACH)	PROHIBITED
Polyvinyl chloride (PVC)	PROHIBITED
Talc	PROHIBITED
Titanium dioxide	RESTRICTED Not in nano form, not in free powder