

# NON-CONFIDENTIAL VERSION OF EXPOSURE SCENARIOS

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*Collectively referred to as “Soft PVC Recyclate Authorization Consortium” (in short : SPAC) for the purpose of this Application for Authorization*

**Submitted by:**

*Vinyloop Ferrara SPA*

**Substance:**

**BIS(2-ETHYLHEXYL) PHTHALATE (DEHP)**

**Use titles:**

*1: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends*

*2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles*

# 1. Introduction

Recycled soft PVC containing DEHP is mainly gained from post-consumer waste by separating soft PVC from other parts, followed by shredding or micronizing the soft PVC. Another manufacturing process includes dissolution of PVC waste and purification by precipitation. Please note that throughout this document the terms “Recycled soft PVC containing DEHP” and “Soft PVC Recyclate” are used interchangeably.

These solid recyclates, consisting of soft PVC granulate and containing up to 20% DEHP (with typical concentrations generally lower), is then used for PVC processing and production of articles by PVC converter companies.

Use of pure DEHP is not relevant here and not covered by this application.

The table below lists the uses, for which authorisation is requested.

Use applied for
#1: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends
#2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

This application seeks authorisation for two uses within a single supply chain: formulation of recycled soft PVC containing DEHP into solid soft PVC mixtures and use of recycled soft PVC containing DEHP (as it is or in these formulations) for production of PVC articles.

The only industrial end use included in this application for authorisation is use of material containing DEHP for production of PVC articles. The range of articles produced from recycled PVC is limited and consists mainly of products made for outdoor use.

A summary may be found in the table below :

## Typical end articles covered by SPAC Application for Authorization

Type of application	Industrial/professional service life	Consumer
Construction and civil engineering outdoor (e.g. foils, road equipment)	X	
Construction indoor (e.g. warehouse flooring)	X	
Construction indoor (e.g. foils, flooring back layers)		X
Consumer products indoor (e.g. mats)		X
Consumer products outdoor(for garden)		X
Footwear	X	X
Other	X	

Note : \* limited volume of production of such articles

The exposure scenarios (with contributing scenarios) established for these uses and for the manufacturing process are listed in the following table.

Use applied for	Use title	ES no.	ES name	Manufacture	Identified uses				Resulting life cycle stage		Sector of Use (SU)	Product Category (PC)	Process Category (PROC)	Article category (AC)	Environmental release category (ERC)
					Formulation	Industrial End use	Professional End use	Consumer end use	Service life (for articles)	Waste stage					
#1	Formulation of recycled soft PVC containing DEHP in compounds and dry-blends	ES1	Formulation of recycled soft PVC containing DEHP in compounds and dry- blends		x						10, 12	32	1, 2, 3, 4, 8a, 8b, 14, 15		3
#2	Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles	ES2	Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles			x					12	32	2, 3, 4, 6, 8a,8b,14, 21	13	5
		ES2 -SL-P	<i>Contributing Scenario: Service life professionals: Professional handling of PVC products made from recycled soft PVC containing DEHP: Installation of building materials and similar activities) / inhalation exposure from volatile DEHP / professional PVC footwear)</i>						x I/P *				21	13	10a, 11a
		ES2 -SL-C	<i>Contributing Scenario: Service life consumers: Exposure from consumer articles made from recycled soft PVC containing DEHP</i>						x C					13	10a, 11a

\* This service life scenario was developed for professional workers, but equally applies to industrial workers because exposure is not expected to differ between professional and industrial workers for this scenario.

## 1.1 Exposure to workers

### Industrial workers

Exposure to DEHP of industrial workers occurs during the manufacture of compounds and dry-blends (formulation stage) as well as during the production of PVC articles (polymer processing by calendering, extrusion, compression and injection moulding).

### Professional and industrial workers

Professional and industrial workers may be exposed to DEHP from PVC articles containing soft PVC recyclate during their service life and exposure from the service life stage is considered to be identical for professional and industrial workers. The following table summarises the contributing scenarios for exposure scenario ES2.

Contributing service life scenarios for professional (and industrial) workers

ES no.	ES name
ES2-SL-P	Service life professionals: Professional handling of PVC products made from recycled soft PVC containing DEHP: Installation of building materials and similar activities (PROC21) / inhalation exposure from volatile DEHP / professional PVC footwear (no PROCs)

## 1.2 Exposure to consumers

This application for authorisation covers only industrial uses of a substance up to the point of incorporation into an article. However, the REACH Regulation stipulates that an Application for Authorisation must be accompanied by a Chemical Safety Report and a Chemical Safety Report requires the inclusion of assessment of service life. In the case of this Application for Authorization for recycled soft PVC containing DEHP, this means that the Chemical Safety Report includes an assessment of consumer exposure to PVC articles containing soft PVC recyclate.

Contributing service life scenarios for consumers

ES no.	ES name
ES2-SL-C	Service life consumers: Exposure from consumer articles made from recycled soft PVC containing DEHP

## 2. Use #1: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends

<b>ES1: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends</b>
Use descriptors related to the life cycle stage and all the uses under it: SU 10,12 – PROC 1, 2, 3, 4, 8a, 8b, 14, 15 – PC 32 – ERC 3
<b>Contributing exposure scenario ES1-W controlling worker exposure</b>
Formulation of recycled soft PVC containing DEHP in compounds and dry-blends (PROC 1, 2, 3, 4, 8a, 8b, 14, 15) Covers the material receipt, preparation, reaction, pelletisation, bulk transfer and storage, as well as equipment cleaning, and associated maintenance activities as well as use in laboratories.
<b>Product characteristic</b>
Physically dispersed in a solid matrix (PVC). Solid, low dustiness [OC1] Limit the substance in product to 20 % [OC21]
<b>Other given operational conditions affecting workers exposure</b>
For dry blending and compounding: Some operations are carried out at elevated temperature [OC7] in closed systems: 100-150°C; During activities involving operator's action, the temperature is estimated to be maximum 40°C.

<b>ES2-W: Formulation of recycled PVC containing DEHP in compounds and dry-blends</b>		
<b>Process</b>	<b>PROC</b>	
Closed continuous process, Indoors	PROC 1 – Use in closed process, no likelihood of exposure	<b>The CSR demonstrates that there is no risk from exposure to DEHP for industrial workers.</b>  <b>The risks are adequately controlled.</b>
General exposures (closed systems); With sample collection; Indoors.	PROC 2 – Use in closed process, continuous process with occasional controlled exposure	
General exposures (closed systems); With sample collection; Elevated process temperature Indoors, with LEV present.	PROC 2 – Use in closed process, continuous process with occasional controlled exposure	
Batch closed process exposures; Indoors, with LEV present.	PROC 3 – Use in closed batch process (synthesis or formulation)	
Batch closed process exposures; Elevated process temperature; Indoors with LEV present	PROC 3 – Use in closed batch process (synthesis or formulation)	
Batch closed process exposures; Elevated process temperature; Indoors	PROC 3 – Use in closed batch process (synthesis or formulation)	
Batch process exposures; Elevated process temperature; indoors	PROC 4 – Use in batch and other process (synthesis) where opportunity for exposure arises	
Emptying bags of recycled soft PVC containing DEHP; Manual; Non-dedicated facility; Indoors with LEV	PROC 8a - Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at non-dedicated facilities	
Emptying bags of recycled soft PVC containing DEHP; Dedicated facility; Indoors with LEV	PROC 8b – Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
Drum/batch transfers of solid formulation; Dedicated facility; Indoors	PROC 8b – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated	

with LEV	facilities	
Production of preparations or articles by tableting, compression, extrusion, pelletisation; Indoors with LEV	PROC 14 – Production of preparations or articles by tableting, compression, extrusion, pelletisation	
Quality control in laboratory; Indoors with fume cupboard	PROC 15 – Use as laboratory reagent	

### 3. Use #2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

<b>ES2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles</b>
Use descriptors related to the life cycle stage and all the uses under it: SU 3, 12 – PC 32 – PROC 2, 3, 4, 6, 8a, 8b, 14, 21 – AC 13 – ERC 5
<b>Contributing exposure scenario ES2-W controlling worker exposure</b>
Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles (PROC 2, 3, 4, 6, 8a, 8b, 14, 21) Covers the transferring and processing of formulations containing DEHP as well as equipment cleaning, and associated maintenance activities. Includes low energy manipulation of the resulting polymers
<b>Product characteristic</b>
Physically dispersed in the solid formulation (PVC) Solid, low dustiness [OC1]. Limit the substance in product to 20 % [OC21]
<b>Other given operational conditions affecting workers exposure</b>
For calendaring, compounding, extrusion, compression and injection moulding: some operations are carried out at elevated temperature in closed systems: up to 180°C. Some activities involving operator's action take place at temperatures higher than ambient: the maximum temperature in those cases is estimated to be at 40°C.

<b>ES2-W: Industrial use of recyclate in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles</b>		
<b>Process</b>	<b>PROC</b>	
General exposures (closed systems); Indoors with LEV	PROC 2 – Use in closed, continuous process with occasional controlled exposure	<b>The CSR demonstrates that there is no risk from exposure to DEHP for industrial workers.</b>
Batch closed process exposures; Indoors with LEV	PROC 3 – Use in closed batch process (synthesis or formulation)	
Batch process exposures; Indoors with LEV	PROC 4 – Use in batch and other process (synthesis) where opportunity for exposure arises	
Calendering operations, Indoors with LEV	PROC 6 – Calendering operations	<b>The risks are adequately controlled.</b>
Emptying bags of recycled soft PVC containing DEHP; Manual; Non-dedicated facility; Indoors with LEV	PROC 8a - Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at non-dedicated facilities	
Emptying bags of recycled soft PVC containing DEHP; Dedicated facility; Indoors with LEV	PROC 8b – Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at	

	dedicated facilities	
Extrusion, tableting, compression, pelletisation operations, Indoors with LEV	PROC 14 – Production of preparations or articles by tableting, compression, extrusion, pelletisation	
Low energy manipulation of articles such as cutting, welding, gluing, Indoor with LEV	PROC 21 – Low energy manipulation of substances bound in materials and/or articles	

<b>Contributing scenario ES2-SL-P controlling worker exposure</b>
<p>ES2-SL-P: Service life professionals: <i>Professional handling of PVC products made from recycled soft PVC containing DEHP: Installation of building materials and similar activities (PROC21) / inhalation exposure from volatile DEHP / professional PVC footwear) (no PROCs)</i></p> <p>Professional handling of PVC products containing soft PVC recyclate: Covers installation of building materials and similar activities (PROC 21), while working in workshops with large PVC surfaces (inhalation exposure to volatile DEHP) and simultaneously wearing PVC footwear (e.g. waterproof boots, clogs) (no PROC)</p> <p>Handling of PVC products containing DEHP by craftsmen, such as the installation of soft PVC foils and sheets in construction or civil engineering applications. Typical tasks include manual cutting, assembling and disassembling soft PVC articles, which are considered to lead to dermal exposure only. The same craftsmen are assumed to wear PVC footwear (e.g. waterproof boots) and additional inhalation exposure may exist in specific situations, e.g. for workers occupied in rooms with large PVC surfaces, such as large-scale PVC flooring or polytunnels. These exposures are primarily relevant for professional workers, but similar situations may exist for industrial workers and are therefore also covered by this scenario.</p> <p>DEHP is only contained in plasticised PVC articles (containing soft PVC recyclate), which are not handled by dust-generating processes, also described by PROC 21.</p>
<b>Article characteristic</b>
<p>Articles handled are made of PVC (plastic).</p> <p>This contributing scenario covers the handling of PVC articles containing soft PVC recyclate primarily by craftsmen, such as flooring products, and soft PVC foils and sheets used in construction and civil engineering applications.</p> <p>It also covers PVC articles containing soft PVC recyclate handled by workers in other professions, e.g. roadmen, landscape gardeners and shop assistants, such as: outdoor products, automotive and traffic-related products (e.g. traffic cones and components of traffic signs) and many other items, as exposure (in terms of skin surface exposed and/or exposure duration/frequency) is obviously lower compared to daily dermal contact for several hours to building materials by craftsmen.</p> <p>This contributing scenario includes waterproof footwear (boots with inner lining and worn with socks), as worn e.g. by professional craftsmen, but also e.g. in the food industry. It also covers non-waterproof footwear, such as clogs and safety shoes worn in the professional environment, e.g. by hospital staff, pool attendants etc.(worn against bare skin).</p>
<b>Other given operational conditions affecting workers exposure</b>
Assumes use at not more than 20°C above ambient temperature, unless stated differently [G15].

<b>Contributing scenario ES2-SL-C controlling consumer exposure</b>
<p>ES2-SL-C: Service life consumers: Exposure from consumer articles made from recycled soft PVC containing DEHP</p> <p>ES2-SL-C covers dermal exposure from consumer contact with PVC articles containing soft PVC recyclate. For some PVC articles, oral exposure (primarily by mouthing) is addressed as well. Exposure is estimated with a sentinel product approach with the following 4 groups (X-1 - X-4) and their sentinel articles: X-1: Gym mats, X-2: Handles, X-3: Plastic sandals, X-4: Seating for outdoor use.</p>
<b>Article characteristic</b>
Articles are made of soft PVC containing soft PVC recyclate (plastic).
<b>Amounts (contained in articles) present at workplace</b>

<p>This parameter is not critical for the exposure assessment. Exposure assessment is based on biomonitoring data from studies in the general population and therefore reflects current practice of use of consumer articles without specific restrictions or conditions.</p> <p>Furthermore, for specific article groups (and their sentinel products), exposure modelling is performed, which is based on the migration rate.</p>
<b>Frequency and duration of use/exposure</b>
<p>Exposure assessment is based on biomonitoring data from studies in the general population and therefore reflects current practice of use of consumer articles.</p> <p>For exposure modelling of specific article groups, frequency and duration of exposure differ depending on the specific article group (X-1 – X-4). Values for these parameters have been derived to represent typical conditions for the European population.</p>
<b>Human factors not influenced by risk management</b>
<p>In the exposure modelling exercise, three age groups (adults, children 6-12 months old, children 2-3 years old) are considered to reflect potentially high exposures.</p>

<b>ES2-SL-C: Service life consumers: Exposure from consumer articles</b>		
<b>Article groups</b>	<b>Sentinel product</b>	
<i>X-0: Exposure from carpets with PVC-backing and similar products (no direct contact)</i>	Flooring with PVC back-coating	<b>The CSR demonstrates that there is no risk from exposure to DEHP for consumers (adult and children).</b>
<i>X-1: Dermal exposure from PVC gym mats and similar articles</i>	Gym mats	
<i>X-2: Dermal and oral exposure from smaller PVC articles containing soft PVC recyclate</i>	Handles	
<i>X-3: Dermal exposure from PVC footwear with direct or indirect skin contact</i>	Plastic sandals	<b>The risks are adequately controlled.</b>
<i>X-4: Dermal exposure from PVC articles containing soft PVC recyclate (prolonged contact)</i>	Seating for outdoor use	