

Report Ecowings

Identification of legal obligations as importer of articles

15 March 2017

Summary

Ecowings imports articles from India that are made of re-used (upcycled) tyre-inner-tubes. Based on literature research it is concluded that these articles do not contain substances of very high concern in concentrations $>0,1\%$. Therefore Ecowings has no obligations under the European REACH regulation that require registration, notification or information of the European Chemicals Agency or the recipient of the article. Research on more hazardous materials (infill of rubber granulate used on playing field) indicated that the health risk of playing sports on synthetic turf fields with an infill of rubber granules is virtually negligible. Because the bags imported by Ecowings are in one piece (not granules), contact is much less frequently and it contains less hazardous substances the risks of using these bags are negligible.

Introduction

The EU's new chemicals legislation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) entered into force on 1 June 2007. It has implications for all chemical substances and articles, manufactured or imported into the EU, in quantities of one tonne or more per year. Ecowings imports articles from outside the EU (India) and can therefore be regarded as an importer under REACH. Ecowings has asked Cosanta to identify the legal obligations under the REACH regulations and advice on testing of products. Koen Verbist (registered occupational hygienist) from Cosanta is responsible for this project.

Identification of legal position under REACH and consumer law

Articles: Ecowing imports articles that are made of re-used (upcycled) tyre-inner-tubes. Articles are defined in the REACH regulation as *'an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition'*. For articles different articles from the REACH regulation apply, which are summarized in table 1.

Waste: The articles are made of re-used materials, which could be regarded as waste. According to REACH article 2 waste as defined in Directive 2006/12/EC of the European Parliament and of the Council is not a substance, mixture or article within the meaning of Article 3 of this Regulation. However, once waste is recovered and in this recovery process another substance, mixture or article is produced, the REACH requirements will apply to the recovered substance in the same way as to any other substance, mixture or article manufactured, produced in or imported into the EU.¹ So in this case the products have to be regarded as imported article under the REACH regulation.

Hazardous substances: Polycyclic aromatic hydrocarbons (PAHs) can be present in rubber materials. These substances are classified as carcinogens (category 1B). In order to protect the health of consumers from the risk arising from exposure to PAHs in articles, a maximum concentration limit of 1 mg/kg (0.0001% w/w) has been set for the accessible plastic or rubber parts. For children a lower limit value of 0.5 mg/kg (0.00005% w/w) is established.

NB: This restriction should only apply to those parts of articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity under normal or reasonably foreseeable conditions of use. Articles or parts thereof which are only in short and infrequent contact with the skin or oral cavity should not be included within the scope of the restriction as the resulting exposure to PAHs would be insignificant. Further guidance in this respect should be developed.²

¹ <https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations/navigator/-/navigator/3193-1611-8597>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R1272&from=NL>

Composition of truck inner tubes

To determine if truck inner tubes contain substances listed as Substances of Very High Concern or contain PAHs a literature study was conducted to the composition of truck inner tubes.

Inner tubes are mainly made of Butyl rubber (IIR) because of its low gas permeability. Its structure does not contain aromatic hydrocarbon. IIR is built of poly-isobutylene and 1-5 %wt isoprene. The isoprene is incorporated in the trans configuration. The abbreviation IIR stands for isobutylene-isoprene rubber. It is produced via cationic polymerization with $AlCl_3$ as initiator and a small amount of nucleophilic substances like water or alkylhalogenides as co-catalysts. Methyl chloride is used as solvent, from which the polymer is precipitated. ³

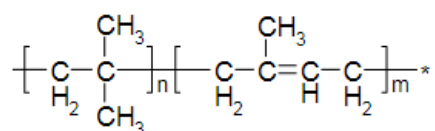


Figure 1-17: Structure of IIR.

Sometimes inner tubes can also contain EPDM (ethylene-propylene-diene-rubber). According to a report by the European Chemicals Agency (ECHA) the type of oils commonly used for EPDM formulations are paraffinic oils, which are practically free of PAHs. The limited data available shows that concentrations of PAHs in EPDM are lower compared to the concentrations measured from recycled rubber granules from tyres. There were only a few studies available concerning the composition of EPDM and TPE. Based on expert information, PAHs should not be present in materials made of EPDM and TPE only.⁴

Conclusion

Based on information on the composition of truck inner tubes it is concluded that these inner tubes do not contain substances that are listed as 'substances of very high concern'. Research has been performed on infill of rubber granulate used on playing field. The results indicated that the health risk of playing sports on synthetic turf fields with an infill of rubber granules is virtually negligible. Rubber infill differs from truck inner tubes. The rubber infill contains hazardous substances in very low quantities. Even for these materials the risks were estimated as 'virtually negligible'. Because the bags imported by Ecowings are in one piece (not granules), contact is much less frequently and it contains less hazardous substances the risks of using these bags are negligible.

³ http://laroverket.com/wp-content/uploads/2015/03/Raw_materials_and_compounds.pdf

⁴ https://echa.europa.eu/documents/10162/13563/annex-xv_report_rubber_granules_en.pdf/dbcb4ee6-1c65-af35-7a18-f6ac1ac29fe4

Obligations under REACH

The Ecowings obligations following the REACH regulations are summarized below:

Registration of substances in articles:

Ecowings imports articles from India. These articles may contain substances. For Ecowings **no obligation** to register these substances applies because:

- It is expected that the total amount per substance in the article does not exceed 1 tonne per year;
- These substances are not intended to be released under normal or reasonably foreseeable conditions of use.

Notification of substances in articles:

REACH identifies Substances of Very High Concern (SVHC). For these substances special requirements apply, for instance notification and communication obligations. For Ecowings **no obligation** to notify ECHA (REACH agency) applies because:

- It is expected that the total amount per substance in the article does not exceed 1 tonne per year;

If the tonnage per substance exceeds the 1 tonnage limit, then it is important to identify the substances present in the article to see if:

- There are substances included in the SVHC-list;
- These substances are present in a concentration >0.1% (w/w)

Communication of information on substances in articles:

When the article contains substances that are listed in the SVHC-list and are present in a (w/w)% >0.1 there is an obligation to provide the recipient of the articles with sufficient information allowing safe use of the article, including as a minimum the name of that substance.

Table 1: Obligations described in the present guidance

Obligation:	Registration of substances in articles (chapter 4)	Notification of substances in articles (chapter 3)	Communication of information on substances in articles (chapter 3)
legal basis in REACH Regulation	Article 7(1)	Article 7(2)	Article 33
actors concerned	article producers and article importers	article producers and article importers	article suppliers
substances concerned	substances intended to be released from articles	substances included in Candidate List of Substances of Very High Concern for authorisation	substances included in Candidate List of Substances of Very High Concern for authorisation
tonnage threshold	1 tonne per year	1 tonne per year	-
concentration in article threshold	-	0.1% (w/w)	0.1% (w/w)

Background legal information

Article 7 - Registration and notification of substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
- a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
 - b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Conclusion: *No registration obligation for Ecowings. Quantities < 1 tonne and no intended release.*

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57⁵ and is identified in accordance with Article 59(1), if both the following conditions are met:
- a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
 - b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).

Conclusion: *No notification obligation for Ecowings. Quantities < 1 tonne.*

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

Conclusion: *No notification obligation for Ecowings because paragraph 2 does not apply.*

Article 33 - Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57¹ and identified in accordance with Article 59(1) in a concentration above 0.1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

⁵ Carcinogenic, Mutagenic, Reprotoxic, (very) Persistent, (very) Bioaccumulative, endocrine disrupting properties, toxic.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request

Conclusion: *When the article contains substances that are listed in the SVHC-list and are present in a (w/w)% >0.1% Ecowings is obliged to provide the recipient of the articles with sufficient information allowing safe use of the article, including as a minimum the name of that substance.*

Article 57 - Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

- a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;
- b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;
- c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008;
- d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;
- f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.