ANNEX XV INVESTIGATION REPORT

Investigation into whether substances in infill material cause risks to the environment and human health that are not adequately controlled – prioritisation and preliminary risk assessment

AUTHOR: EUROPEAN CHEMICALS AGENCY

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P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | echa.europa.eu

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Prioritisation and preliminary risk assessment of substances in infill material

Summary

In response to concerns about the risks posed by substances in plastic and rubber granulates used on synthetic turf pitches, the Commission requested ECHA on 29 August 2017 to examine the available data on substances of concern to human health or the environment in plastic and rubber granulates used as infill in synthetic turf pitches. The aim of the review was to identify whether any such substances should be subject to risk management. The assessment does not include polycyclic aromatic hydrocarbons (PAHs) in rubber and plastic granules, as these are already proposed to be restricted under REACH by the Netherlands[1].

For this report, ECHA (i) gathered information on substances in infill material, (ii) performed a prioritisation exercise to identify, of those substances reported to be present in infill, those that are likely to be of greatest potential concern for human health or the environment and (iii) conducted preliminary human health and environmental risk assessments to identify candidates for potential risk management.

The conclusions of the report are, as follows:

- The preliminary human health risk assessment does not exclude a potential for cobalt and zinc to pose risks to human health in infill and that these substances should therefore be considered for risk management.
- The preliminary environmental risk assessment does not exclude the potential for cadmium, cobalt, copper, lead, zinc, 4-tert-octylphenol, 4,4´-isopropylidene diphenol (BPA), bis(2-ethylhexyl)phthalate (DEHP), benzyl butyl phthalate (BBP) and benzothiazole-2-thiol to pose risks to the environment and that these substances should therefore be considered for risk management.

Any further work to establish whether there is a risk for human health or the environment from these substances in rubber infill that is not adequately controlled is recommended to be done within the context of the preparation of an Annex XV restriction proposal.

It is important to note that alongside this assessment ECHA has, at the request of the Commission, proposed a restriction on intentionally added microplastics, that includes within its scope infill used on synthetic turf pitches[2]. The decision by the Commission and the Member States on the implementation of the proposed microplastics restriction (i.e. whether and under which timescale a ban on the use of microplastics as infill on synthetic pitches was required) will affect the need for risk management for the substances identified in this report in infill, potentially making any further risk management unnecessary[3]. In the event that microplastic infill is banned, non-microplastic uses of recycled ELT (e.g. mulches) may still require further risk management.

ECHA notes that the gathering of the substances in infill material was done after receiving the request from the Commission. In any further work, newly published information needs to be gathered in addition to any updates of the registrations as regards the production of substances in tyres.

[1] At the time of publication, the REACH restriction proposed by the Netherlands on PAHs in rubber granulates is awaiting a decision in the REACH committee.

[2] ECHA agreed with the Commission to postpone the finalisation of this assessment (and any further risk assessment / risk management of substances in infill) until after the opinion-making on the restriction proposal on intentionally added microplastics was concluded.

[3] ECHA's scientific committees for risk (RAC) and socio-economic analysis (SEAC) concluded their opinion making on the proposed restriction on intentionally added microplastics in December 2020. At the time of publication, the proposal is subject to decision making by the Commission and Member States.

1. Background

Following ECHA's report "An Evaluation of the Possible Health Risks of Recycled Rubber Granules Used as Infill in Synthetic Turf Sports Fields" of 28 February 2017 and the intention of the Netherlands to prepare a restriction dossier on plastic and rubber granulates containing PAHs[4], on 29 August 2017 the Commission requested ECHA to examine relevant substances of concern to human health and the environment, other than PAHs, in plastic and rubber granulates used as infill in synthetic turf pitches[5].

This report provides information on the substances reported to occur in infill material, ECHA's prioritisation approach to select certain substances for further risk assessment and the risk screening (preliminary risk assessment) conducted for selected substances.

2. Prioritisation

ECHA identified ~350 substances that could reasonably be expected to occur in rubber infill granules[6].

Two potential approaches to risk assessment and risk management, besides the existing PAH restriction proposed by the Netherlands, were considered: (i) a wide-scope restriction on all CMR substances in infill, or (ii) a targeted restriction on specific substances identified in rubber granules that were considered to pose an uncontrolled risk.

The first approach was rejected for several reasons: firstly, it would be problematic to implement as industry (and enforcement authorities) would need to test rubber granules for **all** CMR substances, and the resources needed to make the risk and impact assessment would be disproportionate given that ECHA and the Netherlands had already stated the concern was low (given previous assessments). Therefore, considering the large number of substances identifed to be present in rubber infill, a prioritisation exercise was proposed to identify the most relevant substances of concern to human health other than PAHs in infill material.

Similarly, further prioritisation and screening was necessary to identify relevant substances of concern for the environment. A wide scope restriction on generic environmental hazard classification e.g. PBT/vPvB substances and/or aquatic chronic toxicity would be difficult to implement, may introduce disproportionate costs (industry would need to test rubber granules for **all** those substances), and would require extensive resources to make the risk and impact assessment.

The aim of the prioritisation is to identify substances for preliminary human health and environmental risk assessment. Based on this preliminary risk assessment, candidates for risk management were identifed.

2.1. Starting pool of substances

Data on occurrence of substances in rubber infill was gathered from chemical analysis studies on market and field samples from Europe and the United States[7], and a small number (n=5)

[4] Submitted on 20 July 2018: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/20503/term

[5] https://echa.europa.eu/documents/10162/13641/request_echa_cooperate_with_the_nl_and_rubber_granules_en.pdf/df803191-d222-0bb5-a838-7a936454f5b9

[6] Assumption is that rubber mulch contains the same substances as rubber infill granules. The restriction proposal from the NL states: Although most of the rubber mulch produced in the EU is derived from ELT, it can also be formulated from virgin material, namely EPDM.

[7] The U.S.EPA&CDC/ATSDR (2019) was published in July 2019. According to the report, a range of metals (21 metals), semi-volatile organic compounds (49 SVOCs), volatile organic compounds (31 VOCs) and bacteria in and on tyre crumb rubber infill material were found in targeted analysis. In addition to targeted chemical analysis, suspect screening and non-targeted analysis were conducted, however these results are regarded as tentative and require further confirmation through analysis of chemical standards.

were included based solely on a relevant identified uses in registration dossiers[8]. ECHA identified ~350 substances that may occur in rubber crumb infill, mainly from end-of-life tyres and in some cases from other recycled rubber material (ECHA (2017a), Sanner (2006), Menichini (2011), Källqvist (2005), Ruffino (2013), RIVM (2017), ESTO (2016), Skenhall (2012), DK-EPA (2008), Plesser (2004), Marsili (2015), US-EPA (2016), EHHI (2017), Magnusson (2015)).

Concerning PAHs, ECHA notes the recent RAC and SEAC opinion[9] on the restriction on PAHs in infill material proposed by the Netherlands and, specifically, the recommended limit values. As this restriction proposal is based solely on the carcinogenicity of these substances, additional measures could be justified based on the risks posed to the environment (PAHs are identified as PBT/vPvB in addition to their carcinogenic/mutagenic classification). However, these were not specifically investigated for the purposes of this report as the focus is on substances other than PAHs. Nevetherless, ECHA proposes that risks to the environment from PAHs should be investigated as part of any future Annex XV report requested by the Commission as a follow up to this prioritisation and preliminary risk assessment.

Substances occurring exclusively in EPDM, TPE, or organic infill material (e.g. cork and coconut fibre) were not included in the pool as they were not considered to be of priority or focus since (1) these materials are alternatives to rubber infill; (2) have a limited market share[10]; (3) limited analytical data is available for these alternatives; and (4) a possible restriction proposal will need to assess the risks of the alternatives[11].

2.2. Prioritisation approach

Substances were prioritised for either human health or environmental preliminary risk assessment based on a scoring system:

(i) **human health hazard and exposure criteria**. Three criteria were used based on human health hazards. A substance that does not score any points on human health hazard criteria 1 or 2 is not an eligible candidate for risk assessment and

(ii) **environmental hazard and exposure criteria**. Six criteria related to environmental hazard, fate, transport and exposure.

The availability of data on the concentration of a substance in infill is considered as a prerequisite for undertaking any risk assessment. Only concentration data from Member States of the European Union/EEA were taken into consideration This decision was made early in the process of gathering and summarising data on the basis that concentration data obtained from the EU/EEA were most relevant to EU/EEA risk management. However, comparison of the available EU data with data from U.S.EPA&CDC/ATSDR (2019) is provided in subsequent sections of this document.

Concentration data was available for 70 substances, thus making these eligible for prioritisation with the aim to identify candidate substances for further risk assessment (concentration data on PAHs was not gathered for the purpose of this report). Most of the concentration data in this document is from ELT based rubber infill material, only in some cases the data is from other recycled rubber material.

For the remaining non-PAH substances literature searches did not provide concentration data from EU/EEA countries and thus no risk assessment could be performed. These substances were excluded from the prioritisation. A description of the information gaps for these substances will

[8] For any further work related to this matter, ECHA will screen the registration data for any updates.
[9] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d5746d
[10] The total market share of the alternatives is estimated at around 10% of infill material by (RIVM, 2018) with EPDM and TPE accounting each for about 4%.
[11] A restriction proposal can also consider to include an alternative in the scope, i.e. a possible limit on a substance could also apply to EPDM or TPE infill in addition to rubber infill. There is some overlap in the presence of substances in rubber infill and infill from EPDM and TPE.

be part of documenting the remaining uncertainties in any future restriction proposal.

The presence of metal substances in infill is typically reported in the available analytical studies as a total metal[12] concentration. As default, for the purposes of the prioritisation scoring, all metals were assumed to be present in infill in the form of the substance with the most severe harmonised classification in ECHA's database, but excluding substances consisting of more than one metal[13]. The top ranking metals in the initial list were subsequently scrutinised, and where the available evidence allowed, the default assumption was overridden as reported in Section 3.1 (e.g. in the case of iron).

ECHA (2017a) assessed the risks to human health from the following substances (in addition to PAHs) in infill material:

- Phthalates: dibutyl phthalate (DBP); diisobutyl phthalate (DiBP); benzylbutyl phthalate (BBP); and di(2-ethylhexyl)phthalate (DEHP)
- benzene
- formaldehyde
- methyl isobutyl ketone (4-methylpentan-2-one)
- benzothiazole and benzothiazole-2-thiol (i.e. 2-mercaptobenzothiazole, 2-MBT)

ECHA (2017a) did not identify a concern for human health for these substances in infill material and thus they were not priority candidates for further human health risk assessment and were therefore excluded from the current prioritisation for human health.

RIVM (2017) assessed the risks to human health of the following substances (in addition to PAHs) in infill material:

- Phthalates: dibutyl phthalate (DBP); diisobutyl phthalate (DiBP); benzylbutyl phthalate (BBP); di(2-ethylhexyl)phthalate (DEHP); diisononyl phthalate (DINP); and dicyclohexyl phthalate (DCHP)
- 2-Mercaptobenzothiazole (2-MTB)
- Bisphenol A (BPA; 4,4'-isopropylidenediphenol)
- Metals: cadmium; cobalt; lead

RIVM (2017) did not identify a concern for human health from these substances and thus they were not priority candidates for further human health risk assessment and were therefore excluded from the current human health prioritisation, with the exception of cobalt. RIVM (2017) assumed a threshold limit of 1.4 μg/kg bw/day based on cardiomyopathy and a tolerable concentration in air (TCA) of 0.5 $\mu g/m^3$ based on interstitial lung disease in humans. The values were taken from RIVM (2001). The reference values derived by RIVM (2001) as well as the

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[12] Total metal is the sum of all metal species. Total metal is typically reported as it is far easier to measure than individual metal species.

[13] Aluminium, sodium, potassium, calcium, magnesium and iron all are metals in the substance "e-glass microfibres of representative composition" and therefore this substance was not considered in the prioritisation. However, since ECHA had some indications that this particular substance may be used in tyres ECHA investigated the possible occurrence further. Glass fibres have been used in Goodyear Polyglas tires. At least in the US, such bias-belted tire were used in the 60ies and the 70ies (source: Wikipedia 2018). An example of use of fiber glass in tyre manufacturing in the US was found (http://roadrunnertires.com/wp-content/uploads/2016/08/2016-Houston-Brochure.pdf) but is not clear to what extent glass fibres could be present in rubber crumb infill in EU, if at all. Based on the available evidence it appears any presence of e-glass microfibres of representative composition in rubber crumb infill material may be considered negligible.

conclusion that cobalt is not a genotoxic agent with a threshold may need to be reconsidered while performing the further risk assessment on substance in infill material. Since the RIVM (2017) report a harmonised classification for cobalt as Carc. 1B, Muta. 2 and Repr. 1B has been agreed by RAC, ECHA (2017b). ECHA (2016) considered water soluble cobalt salts as genotoxic carcinogens which are to be assessed using a non-threshold approach. This is all the more relevant as cobalt salts are used in tyres as bonding agents.

The study by RIVM (2017) focused on the assessment of health risks, but it provided some information on leaching of metals (zinc, copper, cobalt, barium) from the granulate samples to water. These concentrations mainly give an indication of the possible leaching of metals from rubber granulate to the environment (soil and ground water).

Data in the recent U.S.EPA&CDC/ATSDR (2019) study indicates that many chemicals were found in similar concentrations than in the previous studies. The report provided concentration data for five substances that were included in the initial list of identified substances but which did not have concentration data from the EU/EEA countries: aniline, bis(2,2,6,6-tetramethyl-4-piperidyl)sebacate, butylbenzene, cyclohexyl isothiosyanate and hexadecane) (samples collected from tyre recycling plants). Note that the concentrations of PAHs were not collected from the EU/EEA countries for this report and thus no comparison was made for PAHs measured in the US.

This prioritisation approach does not take into account the possible combined (or mixture) effects of substances. According to RIVM (2017), the total concentration of the seven different PCBs is above the soil limit for residential classification in the NL. Since these PCBs belong to the 'nondioxin-like' (NDL) PCBs, they do not appear on the SVHC list and were not included in the subsequent risk assessment. Other PCBs were not found in the RIVM study. This issue is further discussed in section 5.1.

2.3. Prioritisation criteria

2.3.1. Human health criteria

Criterion 1: Classification

For the purposes of the current prioritisation we considered a substance 'classified' for a hazard property when

a) there is a harmonised classification under CLP; or

b) it is self-classified by *any* registrant; or

c) the majority (>50%) of CLP notifiers proposed classification for the endpoint.

The hazard properties and their scoring are as follows:

1. **3 points**/endpoint for

   Carc. cat.1A OR 1B; AND

   Muta. cat.1A OR 1B; AND

   Repr. cat.1A OR 1B; AND

   Skin Sens. cat. 1 OR 1A OR 1B; AND

   Resp. Sens. cat. 1 OR 1A OR 1B

2. **2 points**/endpoint for

   Carc. cat. 2; AND

   Muta. cat. 2; AND

   Repr. cat. 2; AND

   STOT RE cat. 1

Note: If a substance has CMR cat.1A OR 1B then any CMR cat. 2 is ignored for the same substance

3. **1 point** for STOT RE cat. 2
   Note: If a substance has STOT RE cat. 1 then any STOT RE cat. 2 is ignored for the same substance

The maximum possible score for criterion 1 is 17 (5*3 + 2).

Criterion 2: SVHC status

1. Article 57 (a), (b) and (c): one point seems reasonable to give some extra weight because the substance is not only classified as CMRs cat 1A or 1B but also identified as SVHCs. *Score: **1 point**/property*
2. Identified as endocrine disruptor for human health under Article 57 (f). Since CMRs that are SVHC based on their CMR properties will also receive a score of 4 per endpoint, a score of 4 for ED properties seems reasonable. *Score: **4 points***
3. Identified as specific target organ toxicity after repeated exposure under Article 57(f): one point seems reasonable to give some extra weight because not only classified as STOT RE cat 1 but also identified as SVHC.

   *Score: **1 point***
4. Article 57 (d) and (e): PBT/vPvB substances[14]: A maximum score of 4 is considered reasonable based on the following:
   i. CMRs that are SVHC will get a score of 4 per endpoint.
   ii. The PBT and vPvB concerns are similar in nature, and the ‘T’ in PBT will already receive points for the CMR classification (criterion 1) and possibly SVHC identification.
   iii. Although the principal focus of the assessment is direct exposure, it should be acknowledged that the use of rubber crumb in the EU is wide dispersive, there is no containment, and the infill volumes are high (>100 000 t/y, roughly 100 t/field)

   *Score: **4 points** (flat score, i.e., not per property)*

The maximum possible score for criterion 2 is 12 (3+4+1+4).

Criterion 3: Substance under scrutiny

Each individual substance is attributed to one single category and receives a score based on the regulatory scrutiny the substance is under as of 12/04/2018. The category definition and the scoring are provided in the table 1 below. The maximum possible score for criterion 3 is 2 points.

[14] None of the top ranking substances in the initial list received a score because of their PBT or vPvB properties. Therefore, there was no need to scrutinise PBTs to assess whether the basis for the ‘T’ is a human or an environmental hazard or both (with the aim to deduct points in case the concern is for the environment only). In the case of vPvB substances, the concern is that even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since high but unpredictable levels may be reached in man or the environment over extended time periods.

Table 1 Categories and their descriptions

Categories	Description
1. Substances under regulatory action *Score: **2 points** flat when occurring in this category*	A substance was considered under regulatory action if it is included in any of the following: – Annex XIV of REACH, or in the candidate list or formally proposed for SVHC identification; – Annex XVII of REACH*, or formally proposed for restriction; – Annex I, III, IV and V of Regulation (EC) 850/2004 or Annex A, B, C of the Stockholm convention.
2. Substances currently under scrutiny *Score: **1 point** flat when occurring in this category*	A substance was considered under scrutiny if not listed under the category 1 (regulated) and if any of the following applies: - currently under RMOA; - currently under Substance Evaluation or included in the (draft) CoRAP; - currently under PBT or ED assessment by the Expert Groups; - manually screened with follow up actions identified (substance screened prior integrated screening are not considered here); - has in registry of intention a SVHC intention; o Restriction intention; o CLH intention; o CLH under development.
3. Substances considered of no current priority after being assessed *Score: 0*	A substance was included in this category if it was not listed in the categories 1 or 2 or if: - it has been manually screened by ECHA or a Member State (substance screened prior integrated screening are not considered here) and concluded with no need for further action at the moment, and/or - an RMOA or Substance Evaluation concluded no need for regulatory action at the moment, and/or - the PBT or ED Expert Groups concluded based on currently available data that the substance is not PBT/vPvB or ED

* Excluding entries 28 to 30 which cover restrictions of consumer uses for substances having a harmonised classification as CMR cat. 1A/1B. Note also that some specific restriction entries are not captured with the search, e.g. entry 3 of Annex XVII, which is based on the classification of a substance and with the search, exact substances falling under this entry are not visible.

2.3.2. Environmental criteria

Criterion 1: Classification

For the purposes of the current prioritisation, we considered a substance as 'classified' for a hazard property when:

d) there is a harmonised classification under CLP; or

e) it is self-classified by *any* registrant; or

f) the majority (>50%) of CLP notifiers proposed classification for the endpoint.

The hazard properties and their scoring are as follows:

4. *Score:* ***3 points*** *for*

   Long term (chronic) aquatic hazard: category 1 (H410: Very toxic to aquatic life with long lasting effects)

5. *Score:* ***2 points*** *for*

   Long term (chronic) aquatic hazard: category 2 (H411: Toxic to aquatic life with long lasting effects)

6. *Score:* ***1 point*** *for*

   Long term (chronic) aquatic hazard: category 3 (H412: Harmful to aquatic life with long lasting effects): OR

   Long term (chronic) aquatic hazard: category 4 (H413: May cause long lasting harmful effects to aquatic life).

The maximum possible score for this criterion is 3.

Criterion 2: Fate and transport

Substances with physico-chemical properties corresponding to high 'mobility', which could be more likely transported to the environment from a synthetic sports surface than other less mobile substances, were assigned a higher priority than other substances. The SVHC dossier prepared by Germany on undecafluorohexanoic acid and its ammonium salt used water solubility and Koc at a specific temperature and pH range for characterising the high mobility of the substance[15]. However, as there were limited data available from registrations for water solubility and log K_{OC} within the pH and temperature range set in the German SVHC dossier, modified criteria were adopted here, i.e. the temperature was extended from 12 °C to cover a broader range 0-55 °C and the proposed pH range of 4-9 was excluded.

Score: ***4 points*** *for*

Substances for which the highest reported water solubility ≥ 0.15 mg/L and the lowest reported log Koc is ≤ 4.0 at a temperature within 0-55 °C. Substances without data on water solubility and log Koc received no points.

[15] https://echa.europa.eu/documents/10162/3b44eacf-e1f4-4ee7-6daa-f09945c8e3a7

Criterion 3: SVHC status

1. Article 57 (d) and (e): PBT/vPvB substances[16]

   Score: ***4 points*** *(flat score, i.e., not per property)*

2. Identified as endocrine disruptor for the **environment** under Article 57 (f). A score of 4 for ED properties for environment seems reasonable.

   Score: ***4 points***

The maximum possible score for this criterion is 4 (either criterion 3(1) or 3(2)).

Criterion 4: Substance under scrutiny

Each individual substance is attributed to one single category and receives a score based on the regulatory scrutiny the substance is under as of 5 March 2019. The category definition and the scoring are provided in the Table 2 below. The maximum possible score for this criterion is 2 points.

Table 2 Categories and their descriptions

Categories	Description
4. Substances under regulatory action *Score:* ***2 points*** *when occurring in this category*	A substance was considered under regulatory action if it is included in any of the following: – Annex XIV of REACH, or in the candidate list or formally proposed for SVHC identification; – Annex XVII of REACH*, or formally proposed for restriction; – Annex I, III, IV and V of Regulation (EC) 850/2004 or Annex A, B, C of the Stockholm convention.
5. Substances currently under scrutiny *Score:* ***1 point*** *when occurring in this category*	A substance was considered under scrutiny if not listed under the category 1 (regulated) and if any of the following applies: - currently under RMOA; - currently under Substance Evaluation or included in the (draft) CoRAP; - currently under PBT or ED assessment by the Expert Groups; - manually screened with follow up actions identified (substance screened prior integrated screening are not considered here); - has in registry of intention a SVHC intention; o Restriction intention; o CLH intention; o CLH under development.

[16] Twelve substances with PBT/vPvB concern (either article 57d and/or article 57e) were found among the full set of substances (347) screened. Among those were nine PAHs, of which three (benz[a]anthracene, benzo[k]fluoranthene and chrysene) are within the eight PAHs already restricted under the restriction entry 50 of the Annex XVII to REACH and for which a restriction proposal in infill material and mulches is under consideration. Both these restrictions restrict PAHs that are markers for exposure to other PAHs and as such restrict all PAHs, including the nine reported to be present in rubber infill. Other substances were: alkanes, C10-13, chloro (chlorinated paraffins, C10-13), 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol and dodecamethylcyclohexasiloxane (D6).

Table 2 Categories and their descriptions	
Categories	**Description**
6. Substances considered of no current priority after being assessed *Score: 0*	A substance was included in this category if it was not listed in the categories 1 or 2 or if: - it has been manually screened by ECHA or a Member State (substance screened prior integrated screening are not considered here) and concluded with no need for further action at the moment, and/or - an RMOA or Substance Evaluation concluded no need for regulatory action at the moment, and/or - the PBT or ED Expert Groups concluded based on currently available data that the substance is not PBT/vPvB or ED

2.4. Exposure/emission criteria for human health and the environment

ECHA collected information on concentrations of substances in rubber infill material and frequency of occurrence in samples from the available studies in the EU ((Bocca, 2009); (DK-EPA, 2008); (ESTO, 2016); (ETRMA, 2016); (Marsili, 2015); (Menichini, 2011); (Plesser, 2004); (RIVM, 2017); (Ruffino, 2013); (Sanner, 2006)). The concentration and frequency of occurrence in samples are considered proxies for exposure.

Criterion 5: Concentration

This criterion gives points based on five different concentration bands (weighted average concentration) for substances in infill samples from pitches or producers in the EU.

The concentration of a substance in rubber infill is an important determinant of exposure and emission and is therefore considered to be a reasonable proxy for exposure and emission. Other important determinants of exposure and emission are the migration rate of the substance from the infill (which in turn depends on the simulant/exposure route and on the solvent, concentration, etc.), evaporation and the bioavailability (particularly metals), which needs to be considered when assessing the risks of the substances.

The average concentration in each study was weighted by the total number of samples in that study, which allowed to calculate a weighted average concentration from all studies (‘a weighted average of averages’). This weighted average was used to compare with the concentration bands used for this criterion. A weakness in the weighting approach is that it is not always reported whether or not in all samples the substance was detected.

The maximum weighted average concentration in infill samples from pitches or producers was 805 mg/kg for non-metals (N-1,3-(dimethyl-butyl)-N'-phenyl-p-phenylenediamine (6PPD) CAS No. 793-24-8) and for metals over 10 000 mg/kg for zinc[17]. The scoring per concentration band is as follows:

- *<0.1 mg/kg (0.00001%): no points*
- *0.1 - <1 mg/kg: score:* ***1 point***
- *1 - <10 mg/kg: score:* ***2 points***
- *10 - <100 mg/kg: score:* ***4 points***
- *≥100 mg/kg (0.01%): score:* ***6 points***

[17] US multiagency study from 2019: mean concentration 17 000 mg/kg

Criterion 6: Frequency of occurrence in samples

This criterion gives points based on four bands for the frequency of occurrence of substances in infill samples from pitches or producers in the EU.

The frequency of occurrence of a substance in rubber infill samples gives useful information about the fraction of infill that contains the substance and therefore of the scale of the population that will be exposed to the substance. The information has limitations however. Some studies reported detects but did not specify in how many of the total number of samples. In such cases, it was assumed that the substance occurred in all samples as a worst case. There can also be a bias resulting from predefined measurement targets in the studies. In part, this bias may reflect some societal concern which can be seen as relevant in priority setting as well (e.g., high frequency of DEHP).

For non-metals the scoring is based on the sum of the number of samples taken in (Plesser, 2004), (DK-EPA, 2008), (Ruffino, 2013) and (RIVM, 2017). (RIVM, 2017) in practise dominates the numerical value. The highest frequency was 550 for DEHP (546 from (RIVM, 2017)).

For metals the scoring is based on the sum of the number of samples taken in (Bocca, 2009), (DK-EPA, 2008), (ESTO, 2016), (ETRMA, 2016), (Marsili, 2015), (Menichini, 2011), (Plesser, 2004), (Ruffino, 2013). For metals the highest frequency was 62 for zinc.

The scoring per frequency band is as follows:

- *<5: no points*
- *5 - <10: score:* ***1 point***
- *10 - <100: score:* ***2 points***
- *≥100: score:* ***4 points***

3. Results of prioritisation

3.1. Human health

The results from the prioritisation are presented in Table 3 and Table . The 12 substances (zinc oxide and ziram representing zinc) with the highest overall score (score ≥10) in the final list are selected for further risk assessment (Table 33 and Table).

As discussed in section 2.2, the top ranking metals in the initial list (Annex 1, separate excel sheet no 1) were scrutinised to assess whether the default assumption that the metal is present in the rubber crumb infill as the substance with the most severe hazardous classification in ECHA's database holds. In this evaluation information collected from the literature and from expert consultation with the European Tyre and Rubber Manufacturers' Association (ETRMA, 2018) and Dr. Noordermeer, Em. Professor of Elastomer Technology and Engineering of the University of Twente (Noordermeer, 2018) was used. For the following metals, the information was considered sufficient to deviate from the default assumption and this resulted in a change of their ranking in the prioritisation list:

- Iron scored 11 points in the initial ranking. The substance that was used in the initial ranking was: "reaction mass of iron complexes of: 1,3-dihydroxy-4-[(5-phenylaminosulfonyl)-2-hydroxyphenylazo]-n-(5-amino-sulfonyl-2-hydroxyphenylazo)benzene and: 1,3-dihydroxy-4-[(5-phenylaminosulfonyl)-2-hydroxyphenylazo]-n-[4-(4-nitro-2-sulfophenylamino)phenylazo]benzene (n=2,5,6)" with EC No 414-150-3. Iron is the main element in steel which is used in bead wires and the steel belt of tyres and as a result elemental iron (EC No 231-096-4) is a common ingredient in rubber crumb infill and at high concentrations (525.92 mg/kg weighted average), resulting in 8 points for exposure criteria ((VERT, 2018)).

  Elemental iron (EC No 231-096-4) was withheld in the prioritisation. Elemental iron does not score any points on human health hazard criteria 1 or 2 and thus is not an eligible candidate for risk assessment.

- Copper scored 9 points in the initial ranking. The substance that was used in the initial ranking was: "(2,2'-(3,3'-dioxidobiphenyl-4,4'-diyldiazo)bis(6-(4-(3-(diethylamino)propylamino)-6-(3-(diethylammonio)propylamino)-1,3,5-triazin-2-ylamino)-3-sulfonato-1-naphtholato))dicopper(II) acetate lactate" with EC No 407-240-9. Copper is present in tyres in the brass or bronze coating of the bead wires, steel strips or cords (brass is an alloy of copper and zinc, bronze is an alloy of copper and tin) ((ETRMA, 2018); (Noordermeer, 2018); (VERT, 2018); (CANMET, 2005)). As a result copper is a common ingredient in rubber crumb infill and at a weighted average concentration of 20 mg/kg, resulting in 6 points for exposure criteria.

  Elemental copper (EC No 231-159-6) was withheld in the prioritisation. Elemental copper does not score any points on human health hazard criteria 1 or 2 and thus is not an eligible candidate for risk assessment.

- Tin scored 12 points in the initial ranking. The substance that was used in the initial ranking was: "fentin hydroxide (ISO); triphenyltin hydroxide" with EC No 200-990-6. Tin is present in tyres in bronze coating of bead wires (bronze is an alloy of copper and tin) ((ETRMA, 2018); (VERT, 2018); (CANMET, 2005)). In addition tin may be present in the catalyst or additive used by polymer producers ((ETRMA, 2018)). As a result tin is a common ingredient in rubber crumb infill and at high concentrations (weighted average of 23 mg/kg), resulting in 6 points for exposure criteria.

  Elemental tin (EC No 231-141-8) was withheld in the prioritisation. Elemental tin does not score any points on human health hazard criteria 1 or 2 and thus is not an eligible candidate for risk assessment.

Table 3 Final list of substances selected for further human health risk assessment following prioritisation based on hazard and exposure criteria

Rank	Substance[3]	EC	CAS	Classification[1]	SVHC Concerns	Regulatory status	Hazard score	Conc. (mg/kg)[2]	Sample Frequency	Exposure score	Total Score
1	Cobalt dichloride	231-589-4	7646-79-9	Carc. 1B, Muta. 2, Repr. 1B, Resp. Sens. 1, Skin Sens. 1, STOT RE 2	Carcinogenic (Article 57a), Toxic for reproduction (Article 57c)	Regulated or in the process	19	32.1[4]	49	6	**25**
2	Chromium trioxide	215-607-8	1333-82-0	Carc. 1A, Muta. 1B, Repr. 2, STOT RE 1, Resp. Sens. 1, Skin Sens. 1	Carcinogenic (Article 57a), Mutagenic (Article 57b)	Regulated or in the process	20	5.3[5]	59	4	**24**
3	Nickel dichloride	231-743-0	7718-54-9	Carc. 1A, Muta. 2, Repr. 1B, STOT RE 1, Resp. Sens. 1, Skin Sens. 1		Currently under scrutiny	17	3.0[5]	60	4	**21**
4	Zinc oxide	215-222-5	1314-13-2	Repr. 1A, STOT RE 2		Currently under scrutiny	5	10463.6[5]	62	8	**13**
	Ziram	205-288-3	137-30-4	STOT RE 2, Skin Sens. 1		Currently under scrutiny	5	10463.6[5]	62	8	**13**
5	Selenium	231-957-4	7782-49-2	Carc. 1A, Repr. 1A, STOT RE 2, Skin Sens. 1B			10	0.4	45	3	**13**
6	Beryllium	231-150-7	7440-41-7	Carc. 1B, STOT RE 1, Skin Sens. 1		Currently under scrutiny	9	0.1[6]	44	3	**12**
7	Magnesium bis((R)-2-(2,4-dichlorophenoxy)propionate)	413-360-2	-	Skin Sens. 1			3	447.8[5]	48	8	**11**
8	Divanadium pentaoxide	215-239-8	1314-62-1	Muta. 2, Repr. 2, STOT RE 1		Currently under scrutiny	7	3.2[5]	44	4	**11**

9	Lithium heptadecafluorooctanesulphonate	249-644-6	29457-72-5	Carc. 2, Repr. 1B, STOT RE 1			7	1.8	43	4	**11**
10	N-1-naphthylaniline (PANA)	201-983-0	90-30-2	STOT RE 2, Skin Sens. 1B		Currently under scrutiny	5	106.0	1	6	**11**
11	1-methyl-2-pyrrolidone (N-methyl-2-pyrrolidone; NMP)	212-828-1	872-50-4	Repr. 1B	Toxic for reproduction (Article 57c)	Regulated or in the process	6	80.0	1	4	**10**
12	Mercury	231-106-7	7439-97-6	Repr. 1B, STOT RE 1		Regulated or in the process	7	0.1	48	3	**10**

Table notes:
1: Classification as defined by criterion 1.
2 Weighted average. Notes 4, 5 and 6 refer to the US study (2019) information. In case not reference is stated, the US study did not provide any concentration data, or it provides a statement that 'The values reported when %>LoD is ≥ 60%.
3 Not necessarily the substance present in the rubber: metals were assumed to be present in the rubber crumb infill as the substance with the most severe harmonised classification in ECHA's database, but excluding substances consisting of more than one metal (see section 3.10).
4 Based on the US study (2019) the score due to the concentration would be 6 instead of 4.
5 Based on the US study (2019) the score due to the concentration would be the same than with results in EU/EEA.
6 Based on the US study (2019) the score due to the concentration would be 0 instead of 1

Table 4 Final list of substances selected for further human health risk assessment with comments

Rank	Substance[2]	Conc. (mg/kg)[1]	Conc. Range (mg/kg)[1]	Sample Frequency	Total Score	Comments
1	Cobalt dichloride	32.1	3.5 - 268	49	25	Probable main reason for presence: several cobalt compounds[18] are used as metal bonding agents (they react creating links with polymers or brass coating of coated steel cords) ((ETRMA, 2018); (Miracema-Nuodex, 2018); (Noordermeer, 2018)). Other contributions: residue of catalyst for the polymerization of Polybutadiene (BR) ((Noordermeer, 2018); (ETRMA, 2018)). Cobalt dichloride may be used as catalyst[19].
2	Chromium trioxide	5.3	0.3 - 56	59	24	Possible reasons for presence: chromium could be present due to compound contact with stainless steel during tyre and/or crumb production (ETRMA 2018). Possible impurity in zinc oxide used for the sulphur-vulcanization of tyre elastomers ((Noordermeer, 2018)). Possible impurity in steel ((CANMET, 2005)). Since the source of chromium and the speciation is not currently clear, it cannot be excluded that some limited fraction of the total chromium is present as hexavalent chromium. In one study Cr VI was specifically reported but the concentration was below LOD or LOQ (specified as <0.004 mg/kg in (ESTO, 2016)). Elemental chromium does not score points for any hazard criteria.
3	Nickel dichloride	3.0	0.6 – 26.12	60	21	Probable main reason for presence: use in the steel strips coated with brass (stainless steel), cords included in tyres ((ETRMA, 2018)). Other minor contributions: impurity in steel ((VERT, 2018)); residue of Ziegler-Natta catalyst for the polymerization of Polybutadiene (BR) ((Noordermeer, 2018);(ETRMA, 2018)). Elemental nickel scores 13 points (Skin Sens. 1, Carc. 2, STOT RE 1,

[18] Naphthenic acids, cobalt salts (Noordermeer 2018); cobalt bis(2-ethylhexanoate); cobalt(2+) propionate; stearic acid, cobalt salt; neodecanoic acid, cobalt salt; cobalt, borate neodecanoate complexes; cobalt, borate 2-ethylhexanoate complexes; cobalt, borate propionate complexes; Resin acids and Rosin acids, cobalt salts (ETMRA 2018). All these compounds are skin sensitisers. Some are also respiratory sensitisers or toxic to reproduction (e.g. Neodecanoic acid, cobalt salt; Naphthenic acids, cobalt salts). They are soluble cobalt salts.

[19] https://pubs.acs.org/doi/pdf/10.1021/i360001a008

Rank	Substance[2]	Conc. (mg/kg)[1]	Conc. Range (mg/kg)[1]	Sample Frequency	Total Score	Comments
						Regulated or in the process).
4	Zinc oxide/Ziram	10463.6	118 – 21000	62	13	Probable main reason for presence: zinc oxide is used in the production of most rubber products. According to (CANMET, 2005), zinc oxide makes up about 1.2% of passenger tyre which is indeed confirmed by the weighted average concentration of 1.0% (10 463 ppm). Zinc oxide is self-classified as Repr. 1A and STOT RE 2 and is currently under scrutiny, thus scores 13 points (Ziram also scored 13 points). Other contributions: Ziram (zinc dimethyldithiocarbamate) is used in the vulcanization of rubber (IARC (1991)). This is confirmed by REACH registrants who identify the use in the manufacture of rubber products.
5	Selenium	0.4	0 – 3.2	45	13	Possible main reason for presence: selenium is used as a vulcanizing agent and to make rubber more durable[20]
6	Beryllium	0.1	0.001 – 0.37	44	12	Possible main reason for presence: no explanation for the presence of Be in rubber crumb was found. It is not known from Bocca et al. (2009) how often the substance occurred in the 32 samples corresponding to 32 playgrounds in Italy. In Aliapur (2015) submitted by ETRMA (2016) 1 sample was noted as "< 3 mg/kg" and in Menichini et al. (2011) 11 samples were in the range of 0.006 – 0.37 mg/kg.
7	Magnesium bis((R)-2-(2,4-dichlorophenoxy)propionate)	447.8	123 - 966	48	11	Possible main reason for presence: Magnesium oxide is used as a vulcanization agent and hydrated magnesium silicate is used as a filler ((ETRMA, 2018)). Other possible contributions: Possible MgO, MgCl2 or MgBr2 in tyre innerliners ((Noordermeer, 2018)). Impurity present in some fillers ((ETRMA, 2018)). High tensile belt-wire can contain magnesium ((CANMET, 2005)).
8	Divanadium pentaoxide	3.2	0.4-22	44	11	Possible main reason for presence: no explanation for the presence of vanadium in rubber crumb was found.

[20] https://link.springer.com/content/pdf/10.1007%2Fs11015-010-9280-7.pdf

Rank	Substance[2]	Conc. (mg/kg)[1]	Conc. Range (mg/kg)[1]	Sample Frequency	Total Score	Comments
9	Lithium heptadecafluorooctanesulphonate	1.8	0.6 - 11	43	11	Possible reasons for presence: left-over of the butyl-lithium catalyst in use for the anionic solution polymerization of SBR or Polyisoprene ((Noordermeer, 2018); (ETRMA, 2018)) or additive used by polymers producers ((ETRMA, 2018)).
10	N-1-naphthylaniline (PANA)	106.0	NA only measured in one rubber infill sample (out of 5) in (DK-EPA, 2008)	1	11	Possible main reason for presence: according to REACH registrants N-1-naphthylaniline is used for the manufacture of rubber products.
11	1-methyl-2-pyrrolidone (N-methyl-2-pyrrolidone; NMP)	80.0	NA only measured in one rubber infill sample (out of 5) in (DK-EPA, 2008)	1	10	Possible main reason for presence: NMP is used in butadiene production. The main use of butadiene is in the production of synthetic rubbers (such as SBR).[21] Since there is only one measured value it would be good to have some confirmation on the concentration levels. The presence of NMP is confirmed however from headspace analysis and from leaching data in (DK-EPA, 2008).
12	Mercury	0.1	0.03 - 3	48	10	Possible main reason for presence: no explanation for the presence of Hg in rubber crumb was found.

[1] Weighted average
[2] Not necessarily the substance present in the rubber: metals were assumed to be present in the rubber crumb infill as the substance with the most severe harmonised classification in ECHA's database, but excluding substances consisting of more than one metal (see section 3.1).

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[21] https://echa.europa.eu/documents/10162/f6cd9c0f-47b0-48d0-abfa-8e4224b3620e

3.2. Environment

The first ranking of substances[22] was done based on all of the criteria mentioned in section 2.3. However, as no data (water solubility and Koc) were available for criterion 2 (fate and transport) for 16 percent of the substances, a second supplementary ranking excluding criterion 2 was also made. Both rankings of all substances with scores are listed in Annex 1 (separate excel sheet no 2).

Table 5 details the list of 22 substances prioritised for further screening. In this table the starting point is a score of >10 for substances based on prioritisation without the fate and transport criterion 2 (dodecyldimethylamine being the substance where the cut off is done - substances having score 10 or higher are highlighted with red colour in the table). In order to take criterion 2 into account, all substances that ranked above dodecyldimethylamine when undertaking prioritisation including criterion 2 were added to the table. Note that the table reports scores from ranking both with and without criterion 2.

Table 5 Ranking of screened substances with and without fate and transport criteria (criterion 2)

Ranking with criterion 2 (score)	*Ranking without criterion 2 (score[23])*	*Substance*
1 (16)	2 (12)	Ziram
2 (15)	1 (15)	4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-Octylphenol)
3 (15)	4 (11)	Cobalt dichloride
4 (15)	5 (11)	Lead
5 (15)	6 (11)	Copper
6 (14)	8 (10)	4,4'-isopropylidenediphenol (BPA)
7 (14)	9 (10)	N-1-naphthylaniline (PANA)
8 (13)	12 (9)	Chromium trioxide
9 (13)	13 (9)	N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine
10 (12)	3 (12)	Bis(2-ethylhexyl) phthalate (DEHP)[24]
11 (12)	15 (8)	Diarsenic trioxide
12 (12)	16 (8)	Arsenic
13 (12)	17 (8)	Barium[25]
14 (12)	18 (8)	Cadmium
15 (12)	19 (8)	Cobalt[26]
16 (11)	7 (11)	Zinc
17 (11)	34 (7)	Divanadium pentaoxide
18 (11)	35 (7)	Maneb
19 (11)	369 (7)	Benzyl butyl phthalate (BBP)
20 (11)	47 (7)	Benzothiazole-2-thiol (2-Mercaptobenzothiazole, 2-MTB)
21 (10)	10 (10)	A mixture of isomers of iron (1:2) complexes of a mixture of: isomers of: 1,3-dihydroxy-4-[(5-phenylaminosulfonyl)-2-hydroxyphenylazo]-n-(5-amino-sulfonyl-2-hydroxyphenylazo)benzene (n=2,5,6); isomers of: 1,3-dihydroxy-4-[(5-phenylaminosulfonyl)-2-hydroxyphenylazo]-n-[4-(4-nitro-2-sulfophenylamino)phenylazo]benzene (n=2,5,6)
22 (10)	11 (10)	Dodecyldimethylamine

[22] Substances with the same score would receive the same ranking number, but for readability the ranking is expressed as 1,2,3 etc.
[23] Score 7 being the minimum. 4 substances got score 10 in ranking with criterion 2 and score 6 in ranking without criterion 2: diisobutyl phthalate, benzothiazol, 1-methyl-2-pyrrolidone and strontium.
[24] Based on the US study (2019) the score due to the concentration would be 4 instead of 2.
[25] Based on the US study (2019) the score due to the concentration would be 2 instead of 6.
[26] Based on the US study (2019) the score due to the concentration would be 6 instead of 4.

In general, as outlined above, metals were assessed based on the default assumption that the metal is present as the substance with the most severe hazardous classification. However, this assumption was not considered to be sufficiently robust for iron. Iron, and iron-containing substances were therefore removed from the list of prioritised substances[27].

The final list of substances prioritised for further screening are presented in Table 36. Note that metal containing substances are only listed once in the table.

[27] Iron scored 10 points in the initial ranking. The substances that were in the initial ranking are:

- "A mixture of isomers of iron: 1,3-dihydroxy-4-[(5-phenylaminosulfonyl)-2-hydroxyphenylazo]-n-(5-amino-sulfonyl-2-hydroxyphenylazo)benzene (n=2,5,6); isomers of: 1,3-dihydroxy-4-[(5-phenylaminosulfonyl)-2-hydroxyphenylazo]-n-[4-(4-nitro-2-sulfophenylamino)phenylazo]benzene (n=2,5,6)" with EC No 414-150-3 and
- "Diiron trioxide", with EC No 215-168-2.

Iron is the main element in steel which is used in bead wires and the steel belt of tyres and as a result elemental iron (EC No 231-096-4) is a common ingredient in rubber crumb infill and at high concentrations (525.92 mg/kg weighted average), resulting in 8 points for exposure criteria ((VERT, 2018)).

Elemental iron (EC No 231-096-4) was withheld in the prioritisation. Elemental iron does not score any points on environmental hazard criteria 1, 2 or 3 or fate and transport criteria and thus is not an eligible candidate for risk assessment.

Table 6 Final list of prioritised substances for further environmental screening

Rank	Substance[28]	EC	CAS	Environmental Classification[8]	SVHC Concerns[8]	Regulatory status	Hazard Score (with criterion 2)	Conc. (mg/kg)	Frequency of occurrence [29]	Emission score	Total Score, (with criterion 2)
1	Zinc (worst case = Ziram)	231-175-3 (205-288-3)	7440-66-6 (137-30-4)	(Aquatic Acute 1, Aquatic Chronic 1)	(Currently under scrutiny)		3(8)	10 463.6	62	8	11 (16)
2	4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-octylphenol)	205-426-2	140-66-9	Aquatic Acute 1, Aquatic Chronic 1	Endocrine disrupting properties (Article 57(f) - environment)	Regulated or in the process	9	11.5	10	6	15
3	Cobalt (worst case = cobalt dichloride)	231-158-0 (231-589-4)	7440-48-4 (7646-79-9)	(Aquatic Acute 1, Aquatic Chronic 1) Aquatic Chronic 4		(Regulated or in the process) Currently under scrutiny	6 (9)	32.1	49	6	12 (15)

[28] The substance information marked in red is the information collected or calculated from the worst case harmonised classification of the metal speciation of the relevant metal.
[29] See explanation in Criterion 6.

Rank	Substance[28]	EC	CAS	Environmental Classification[8]	SVHC Concerns[8]	Regulatory status	Hazard Score (with criterion 2)	Conc. (mg/kg)	Frequency of occurrence [29]	Emission score	Total Score, (with criterion 2)
4	Lead	231-100-4	7439-92-1	Aquatic Acute 1, Aquatic Chronic 1		Regulated or in the process	9	26.4	49	6	15
5	4,4'-isopropylidenediphenol (BPA)[30]	201-245-8	80-05-7		Endocrine disrupting properties (Article 57(f) - environment),	Regulated or in the process	12	0.5	7	2	14
6	N-1-naphthylaniline (PANA)[31]	201-983-0	90-30-2			Currently under scrutiny	8	106	1	6	14
7	Chromium (worst case = chromium trioxide)	231-157-5 (215-607-8)	7440-47-3 (1333-82-0)	(Aquatic Acute 1, Aquatic Chronic 1)		(Regulated or in the process)	0 (9)	5.4	59	4	4 (13)

[30] Not reported in non-targeted analysis of VOCs and SVOCs by multi-agency US report (2019)
[31] Not reported in non-targeted analysis of VOCs and SVOCs by US multi-agency report (2019)

Rank	Substance[28]	EC	CAS	Environmental Classification[8]	SVHC Concerns[8]	Regulatory status	Hazard Score (with criterion 2)	Conc. (mg/kg)	Frequency of occurrence [29]	Emission score	Total Score, (with criterion 2)
8	N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine	212-344-0	793-24-8				7	805	3	6	13
9	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7		Endocrine disrupting properties (Article 57(f) - environment),	Regulated or in the process	6	7.8	550	6	12
10	Arsenic (Same scores for diarsenic trioxide)	231-148-6 (215-481-4)	7440-38-2 (1327-53-3)	Aquatic Acute 1, Aquatic Chronic 1 (Aquatic Acute 1, Aquatic Chronic 1)		Regulated or in the process	9	0.8	52	3	12
11	Barium	231-149-1	7440-39-3				4	245.4	49	8	12
12	Cadmium	231-152-8	7440-43-9	Aquatic Acute 1, Aquatic Chronic 1		Regulated or in the process	9	0.7	60	3	12
13	Copper	231-159-6	7440-50-8			Regulated or in the process	6	19.8	60	6	12
14	Vanadium (worst case = divanadium pentaoxide)	231-171-1 (215-239-8)	7440-62-2 (1314-62-1)	(Aquatic Chronic 2)		(Currently under scrutiny)	4 (7)	3.3	44	4	8 (11)
15	Manganese (worst case = Maneb)	231-105-1 (235-654-8)	7439-96-5 (12427-38-2)	(Aquatic Acute 1, Aquatic Chronic 1)			4 (7)	5.2	49	4	8 (11)
16	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Aquatic Acute 1, Aquatic Chronic 1		Regulated or in the process	9	0.8	8	2	11

Rank	Substance[28]	EC	CAS	Environmental Classification[8]	SVHC Concerns[8]	Regulatory status	Hazard Score (with criterion 2)	Conc. (mg/kg)	Frequency of occurrence [29]	Emission score	Total Score, (with criterion 2)
17	Benzothiazole-2-thiol (2-Mercaptobenzothiazole, 2-MTB)	205-736-8	149-30-4	Aquatic Acute 1, Aquatic Chronic 1		Currently under scrutiny	8	2.6	7	3	11
18	Dodecyldimethylamine[32]	203-943-8	112-18-5			Currently under scrutiny	4	125	1	6	10

[32] Not reported in non-targeted analysis of VOCs and SVOCs by US multi-agency report (2019)

4. Further assessment of the prioritised substances

4.1. Human health

Following the identification of the 12 substances through the prioritisation criteria, ECHA compared the concentrations of the prioritised metal substances in rubber infill with background levels in soil (Annex 2). If the concentration was lower than the background value, this was noted and no further action was taken. If the concentrations were higher then a further assessment was made.

Based on this assessment (see Annex 2), it was concluded that no further human health risk assessment will be required for chromium, nickel, selenium, beryllium, magnesium, vanadium and lithium.

4.1.1. Zinc

4.1.1.1. Zinc oxide

Zinc oxide is used in the production of most rubber products. According to CANMET (2005), zinc oxide makes up about 1.2% of passenger tyre. This is confirmed by the weighted average concentration of 1.0% (10 500 mg/kg).

The reason zinc oxide was selected as a candidate substance for further human health risk assessment was due to the self-classification of zinc oxide as Repr. 1A and STOT RE 2. Upon investigation this self-classification is due to the presence of lead monoxide in lower grades of zinc oxide. Lead monoxide has no harmonised classification but is self-classified amongst others as Repr. 1A and STOT RE 1. Since lead is already assessed separately, zinc oxide could be considered for deprioritisation.

However, the weighted average concentration of Zn in infill is 10 500 mg/kg (range of 118 – 21 000 mg/kg), which is above the migration limit in the toys legislation of 3750 mg/kg (see Annex 3). The human NOAEL for zinc is around 50 mg/day (SCF (2003)[33]). To get a quick idea of the possible risks, one can conservatively assume that a maximum of 21 g zinc/kg infill and 0.1 g infill/day is ingested[34], then a maximum 2 mg zinc/day could be ingested due to playing on artificial pitches. For children 7 mg zinc/day is indicated to be the upper recommended limit of intake (SCF (2003)). As there is a background exposure from especially food intake, it seems a more refined human health risk assessment for zinc may be necessary to exclude a concern for zinc toxicity (which may manifest as e.g., hypocupraemia, leucopaenia, neutropaenia, sideroblastic anaemia), especially for sensitive subpopulations (e.g., persons with haemochromatosis or insulin dependent diabetes).

4.1.1.2. Ziram (ZDMC)

Ziram is registered in the tonnage band 100 - 1 000 tonnes per year. The registration of Ziram by Taminco BVBA does not cover car tyre production (Taminco-BVBA (2019)). Performance Additives Italy S.p.A. stated that Perkacit ZDMC (Ziram, ZDMC) is not used in the manufacturing of tyres and that they will update the registration dossier accordingly. However, the other two registrants in principle cover car tyre production.

[33] https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out177_en.pdf

[34] ECHA (2017a) assumed that children may swallow 50 mg granules in one event which is around 50 granules. For adults, ECHA (2017a) estimated the amount to be 10 mg. RIVM (2018) assumed ingestion of 90 mg/event for children (<11 y) and goal keepers, and 50 mg/event for adults and children older than 11 years.

The zinc content of ziram is about 21%[35], and thus maximum 210 tonnes/year of zinc as ziram could go into car tyre production. The EU tyre production amounts to almost 5 million tonnes in 2016 (ETRMA[36]). Thus, zinc as ziram could contribute overall with roughly 0.004% (210/5 000 000) or 40 mg Zn/kg infill. The contribution of ziram to the weighted average concentration of zinc in rubber infill (10 500 mg Zn/kg infill) could thus roughly be about 0.4%. However, most of the zinc will not be present as ziram. Indeed, ziram reacts during rubber production and after vulcanisation, the concentration of ziram is <0.001% (<10 mg/kg) based on rubber weight as indicated by Taminco-BVBA (2019). ECHA has no evidence that this residual concentration is also applicable to rubber used in tyres, but since the function as accelerator in rubber is the same, the residual concentration is not likely to be substantially different.

When used in rubber production, at least 0.1% ziram is needed[37] and the final concentration of ziram is <0.001%, which means a reduction with at least a factor of 100 after vulcanisation. In conclusion, free ziram residuals could contribute overall with roughly 0.0002% (1000/5 000 000*100), or 2 mg free ziram/kg infill.

Assuming 10 mg ziram/kg infill and 0.1 g infill/day is ingested, then 1 µg ziram/day would be ingested, or about 0.1 µg/kg bw/day. According to the lead registrant CSR the most sensitive effect is seen in a 52 weeks study in dog with a NOAEL for liver effects of 1.6 mg/kg bw/day, thus leading to a margin of safety of 16 000. It can be concluded that systemic toxicity from possible ziram residues in rubber infill will not be of concern.

It is less straightforward to conclude whether a concentration 10 mg ziram/kg infill can be of concern for skin sensitisation. This depends on the migration of ziram from rubber granules to the skin, the concentration of unreacted ziram penetrating the stratum corneum, and the skin sensitising potency of ziram. The skin sensitising properties of ziram are based on a split adjuvant test in female guinea pig with epicutaneous induction with 25% ziram in corn oil and challenged with 0, 1, 5 and 10% (n=20/dose group). At the 24h reading, 70% of the animals was positive in the 10% dose group. No LLNA test is available and thus no quantitative risk assessment is possible. No human sensitisation data on ziram is available. Of note is that a guinea pig skin sensitisation study with several rubber materials used in playground surfaces is available that suggests that rubber infill do not constitute a skin sensitisation risk (see section 4.1.5), but it is not known if the infill contained residues of ziram (at the same time, it is not known whether rubber infill on the EU market contains ziram either).

4.1.1.3. Conclusion regarding zinc

A more refined human health risk assessment for zinc may be necessary, in particular for zinc oxide. As a starting point for further risk assessment for zinc oxide, opinions from SCF (2003) and EFSA (2014)[38] are available, as well as the EU-RAR (2008).

4.1.2. Cobalt

Cobalt compounds are used as metal bonding agents (they react creating links with polymers or brass coating of coated steel cords) in rubber tyres. Cobalt may also be a present as residue of the use of e.g. cobalt dichloride as catalyst during rubber production.

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35 https://static1.squarespace.com/static/58177600579fb3b841330a7d/t/59bfca06f43b5503bd1521e4/1505741318865/ZDMC_MDS_PA.pdf

36 http://www.etrma.org/uploads/Modules/Documentsmanager/20180329---statistics-booklet-2017---alternative-rubber-section-final-web.pdf

37 https://static1.squarespace.com/static/58177600579fb3b841330a7d/t/59bfca06f43b5503bd1521e4/1505741318865/ZDMC_MDS_PA.pdf

38 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3844

The weighted average concentration of cobalt in rubber infill is 32 mg Co/kg (range of 4 – 268 mg Co/kg infill), whereas the average level in topsoil is 6 mg Co/kg. Based on this information the concentration of cobalt in rubber infill is typically well above the levels in topsoil.

The restriction proposal on five soluble cobalt salts (ECHA (2018)) and the reference dose response RAC for these five salts (ECHA 2016, 2017b) can be used as a starting point for risk assessment from exposure via inhalation. There are also other relevant opinions and assessments available (e.g. the opinion of RAC on elemental cobalt (ECHA (2017c)).

ECHA (2018) considered water soluble cobalt salts as genotoxic carcinogens which are to be assessed using a non-threshold approach. It should be noted that all the five cobalt salts in the restriction proposal are subject to classification as Muta. 2 and further that the classification as Carc. 1B is exposure route specific and only pertains to inhalation exposure. Due to the water solubility profiles of the substances, they are all considered soluble substances in biological systems. Thus, the five cobalt salts are described and evaluated as a category, and the divalent cobalt cation (Co2+) is considered the common critical entity of the salts in relation to the carcinogenic and mutagenic potential. Thus, the different counter ions of the cobalt salts (i.e. sulphate, nitrate, chloride, acetate, and carbonate) are not considered further with regard to these effects. In the further risk assessment the solubility of the cobalt compounds in rubber infill will need to be compared (insofar possible) with the water solubility of the 5 cobalt salts, and an assessment of their corresponding carcinogenic potency will need to be made.

With regard to the oral route, the lead registrant of cobalt dichloride (EC No 231-589-4) used a NOAEL of 3 mg/kg bw/day from an oral sub-chronic study (90 days) in the rat based on findings related to the haematopoiesis and reduced body weight and body weight gain at the mid and high dose group, and derived an oral DNEL of 66 µg/kg bw/day (reportedly using an overall assessment factor (AF) of 25, but an AF of 45.5 appears to have been used rather, possibly to account for the test substance containing cobalt chloride hexahydrate). Using an AF of 200 (AF of 2 for sub-chronic to chronic extrapolation, allometric scaling factor of 4 for the rat, AF of 2.5 for remaining differences, AF for intraspecies of 10), one could derive a tentative DNEL of 15 µg $CoCl_2$/kg bw/day for repeated dose toxicity (or with the factor of 1.82 to account for the test substance, a DNEL of 8 µg CoCl2/kg bw/day could be derived). The tentative DNEL would correspond to 6.6 µg Co/kg bw/day[39] (or 3.6 µg Co/kg bw/day to account for the test substance).

Furthermore, the lead registrant reportedly derived an oral DNEL based on a NOAEL identified in a pre-natal developmental toxicity study in rabbits of 5 mg $CoCl_2$ $6H_2O$/kg bw/day for (i) local gastro-intestinal irritation in pregnant dams and (ii) increased number of early resorptions, but the DNEL value appears not to have been reported in the registration because it was higher than the DNEL for repeated dose toxicity. Using an AF of 60 (default AFs: allometric scaling factor of 2.4 for the rabbit, AF of 2.5 for remaining differences, AF for intraspecies of 10), one could derive a tentative oral DNEL of 83 µg $CoCl_2$ $6H_2O$/kg bw/day for developmental toxicity, or 19 µg Co/kg bw/day[40].

To get a quick idea of the possible risks, one can conservatively assume that a maximum of 268 mg Co/kg infill and 0.1 g infill/day is ingested, then a maximum of 27 µg Co/day or 2.7 µg Co/kg bw/day could be ingested due to playing on artificial pitches. This suggests that a risk from oral exposure from ingestion of rubber granules is not very likely, but a more refined assessment will be necessary to firm up on the DNELs (e.g. the relevant substances in rubber infill and their potency, selection of the point of departure, the AFs

[39] Atomic mass of Cl = 17, and of Co= 27, thus the weight fraction of Co in CoCl2 is 27/(27+34) = 0.44

[40] Atomic mass of Cl = 17, Co= 27, H = 1, O = 8 thus the weight fraction of Co in CoCl2 6H2O is 27/(27+34+60) = 27/121 = 0.22

chosen), the refine the exposure estimates, and to include the contribution of other routes to systemic exposure.

The skin and respiratory sensitisation properties of cobalt compounds will also need to be addressed in a further risk assessment, probably qualitatively. Regarding skin sensitisation see also section 4.1.5. Importantly, the metal bonding substances react, and thus the fraction of Co that is bioaccessible following inhalation or skin contact may be limited.

Conclusion: A human health risk assessment for cobalt will be necessary. As a starting point for risk assessment, several documents are available (e.g. ECHA 2016, 2017b, 2017c, 2018).

4.1.3. PANA (n-1-naphthylaniline) and NMP (1-methyl-2-pyrrolidone)

PANA and NMP are detected in one rubber infill sample (out of 5) in Danish EPA (2008) in concentrations of 106 mg/kg infill and 80 mg/kg infill, respectively. No other data is available. The representativeness of the finding is unclear and therefore the typical concentration in rubber infill is not known.

PANA is manufactured in or imported to the European Economic Area, at ≥ 100 tonnes per annum. According to REACH registrants PANA is used for the manufacture of rubber products. It seems PANA is not covalently bound in rubber but rather is present as antioxidant or protective agent/stabilizer which means it can be expected to migrate out of the infill. PANA is self-classified by registrants as skin sensitiser 1B and STOT RE 2 (kidney and blood system). The repeated dose toxicity can be assumed to follow a threshold mode of action.

NMP is manufactured in or imported to the European Economic Area, at ≥ 10 000 to < 100 000 tonnes per annum. NMP is amongst others used as an intermediate in butadiene production. The main use of butadiene is in the production of synthetic rubbers (such as SBR). NMP has harmonised classification as Repro. 1B, STOT SE 3, as well as Skin and Eye Irrit. 2. RAC derived DNELs for NMP (i.e. it is a threshold substance)[41].

Conclusion: A human health risk assessment for PANA and NMP cannot currently be carried out because their typical concentration in rubber infill is not known. Nevertheless, considering the threshold mode of action for systemic effects for these substances and that the limited available data indicates that concentrations in rubber infill are low (0.01% and 0.008%) these substances are considered to be a low priority for risk management.

4.1.4. Mercury (Hg)

The weighted average mercury concentration in rubber infill is 0.1 mg Hg/kg infill (range: 0.03 – 3 mg Hg/kg infill), which is higher (about double) than in soil in the EU. There are no known intentional uses of mercury compounds in rubber. The source of the mercury contamination in rubber infill is unknown.

In comparison, the EU limit for mercury in most fish species for human consumption is 0.5 mg/kg and for some predatory fish species for human consumption 1 mg/kg (Commission Regulation (EC) No 1881/2006).

Assuming 3 mg Hg/kg infill, i.e. the maximum concentration in rubber infill, and 0.1 g infill/day is ingested, then 0.3 µg Hg/day would be ingested, or about 0.03 µg/kg bw/day. EFSA's tolerable weekly intake (TWI) for inorganic mercury is 4 µg/kg bw, which

[41] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1806abf64

corresponds to 0.6 µg/kg bw/day. This suggests that even with very conservative assumptions the contribution of rubber infill to the tolerable weekly intake for inorganic mercury is 5%. It is not likely that a considerable fraction of mercury in rubber infill would be present in the form of methylmercury[42].

Conclusion: It can be concluded that exposure to mercury via rubber infill is not of concern. No further human health risk assessment will be required.

4.1.5. Skin sensitisation of rubber infill

Rubber can contain several contact allergens such as thiuram compounds, mercapto compounds (e.g. mercaptobenzothiazole), sulfenamides (e.g. N-cyclohexylbenzothiazole-2-sulfenamide), dithiocarbamates (e.g. ziram), N-isopropyl-N'-phenyl-p-phenylenediamine (IPPD), and others such as PANA. In addition, latex allergens (allergenic proteins) may be present in rubber infill.

ECHA is not aware of any case reports or epidemiological data on contact dermatitis from rubber tyres in the general population.

Skin sensitisation testing was carried out with rubber products applied on the skin of guinea pigs in a modified Buehler test (CIWMB (2007)). Three materials used in rubberised playground surfaces were tested: (1) loose crumb rubber made from recycled tires; (2) tiles moulded from tire shreds mixed with a binder; and (3) tiles moulded from particles of the synthetic rubber EPDM mixed with a binder. None of the test products caused skin sensitisation, while the positive control (alpha-Hexylcinnamaldehyde) produced positive reactions in 40-50% of the animals. These data suggest that rubber products made from recycled tires do not constitute a skin sensitisation risk to children. However, the tested articles from the US market are not necessarily representative for rubber infill on the EU market.

4.2. Environment

To evaluate the need for further risk assessment of the prioritised substances, further screening was undertaken, as follows.

Approach 1 –Risk screening based on leaching data and aquatic effects thresholds

This approach was followed when reliable leaching data from rubber matrices was available. If not, Approach 2 (see below) was applied. Under this approach the concentration of a prioritised substance under 'reasonable worst case' leaching conditions was compared to a relevant aquatic effects thresholds, such as a 'predicted no effect concentration' (PNEC) or environmental quality standard (EQS) value from the Water Framework Directive (Dir 2000/60/EC)[43]. Exceeding the effect threshold under worst case leaching is considered as a reasonable trigger to further, more refined, risk assessment. Where worst case leaching conditions result in concentrations below a relevant aquatic threshold this was considered to be indicative of limited potential for risks to arise in the environment.

The volume to weight ratio in a leaching study determines if the leaching data should be

[42] For the sake of comparison, when one would assume that all Hg in rubber infill were in the form of methylmercury, then the contribution of rubber infill to the tolerable weekly intake for inorganic mercury will be 23% (the TWI for methylmercury is 1.3 µg/kg bw, which corresponds to 0.13 µg/kg bw/day).
[43] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008L0105-20130913&from=EN

considered as a reasonable worst-case scenario. A value of 10 L/kg (as established in EN 12457-2) is conventionally applied for determining waste acceptance under the (EU-Landfill-Directive-Criteria, Accessed: 14 May 2019) and may be considered as reasonable worst case leaching conditions as the volume of leachate is low compared to the volume of solid material[44].

Effects thresholds applied were either the $PNEC_{water}$ value from the relevant REACH registration dossier or, where no $PNEC_{water}$ was available, the WFD EQS value. If neither of the previous values were available, other sources of $PNEC_{water}$ were used and are detailed on a case-by-case basis.

Where the leaching value was determined to be greater than the $PNEC_{water}$ used, then further risk assessment is considered to be needed for the substance. Equally, where the observed range of leaching concentrations is within the range of $PNEC_{water}$ used, then further risk assessment is considered to be needed. Where the observed range of leaching concentration are all significantly lower than the derived effects threshold, then no further risk assessment is considered to be needed.

Approach 2 –Risk screening based on soil effects thresholds

This approach was applied when no leaching data from rubber matrices was available. The concentration of the substance in rubber matrices was compared to the $PNEC_{soil}$ from relevant REACH registration dossiers or relevant soil quality standards (e.g. from the Netherlands).

Where the concentration of the substance in infill was below the effect threshold values, the substance is not proposed to be assessed further. Should the concentration in infill material be greater than $PNEC_{soil}$ then the substance would be a candidate for further risk assessment. Where the concentration in infill varied both above and below these values, a case-by-case assessment was done.

Common for both approaches

- For metals, the concentrations of the prioritised metal substances in rubber infill were compared with typical topsoil concentrations (see Annex 2). When concentrations of metals in rubber infill are similar to or lower than the typical levels present in soil, and in the absence of information suggesting that the toxicity of the metal or its bioaccessibility would be significantly greater in rubber infill, further risk assessment can be considered as low priority.
- The frequency of occurrence of the substance in rubber samples is also taken into consideration and the substance is not proposed for further risk assessment if the number of measured concentrations is too low (i.e. 1-2 samples).

Table 7 reports the results of the risk screening. The conclusions drawn from the screening are either that 1) further risk assessment is needed, 2) no further risk assessment is proposed or 3) a candidate for further risk assessment, but not enough sample data to do currently further risk assessment.

[44] https://www.alsenvironmental.co.uk/about-us/news/Waste-Sampling-and-Testing-for-Disposal-to-Landfill_365

Table 7 Final list of substances identified as candidates for further environmental risk assessment

Rank	Substance[45]	Conc. (mg/kg)	Conc. Range (mg/kg)	Frequency of occurrence[46]	Total Score[9]	Leaching information	Comments
1	Zinc (worst case = Ziram)	10 463.6	118 – 21000	62	11 (16)	**(RIVM, 2017)** Measured in (filtered) water at pH of approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median concentration was 21 mg/kg dry matter and maximum 129 mg/kg (average values of each pitch – detected in at least 5 % of the samples). (Corresponding concentrations 2 100 µg/L and 12 900 µg/L (respectively)). **(Ruffino, 2013)** Measured in deionised water between pH [6.63 – 6.41]. The temperature was not reported. The volume to weight ratio was 10 L/kg. The concentration range from 4 samples of SBR leachates were [1 143 – 2 729] µg/L with an average of 1 732 µg/L. **(Kruger et al., 2012)** Measured in water at pH [6.76 - 8.13]. The temperature was not reported. The volume to	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance (zinc) is 20.6 µg/L. The leaching measurements, for which the L/S (liquid to solid ratio) was 10, are between 2-3 order of magnitude higher than the $PNEC_{freshwater}$ values. Even with lower L/S ratio (2 L/kg) the thresholds are exceeded. Topsoil: the concentration in rubber infill is not similar or lower than in soil (the concentration in rubber infill is above the maximum value measured in topsoil concentrations, see Annex 2). Number of samples: The number of samples (62) is considered to be sufficient for reliable risk assessment. Other risk management measures: The risk assessment for human health for infill material recommended doing further risk assessment for this substance. However, it might not sufficiently reduce the risk for the environment. Possible reason for presence: the main reason for the presence of zinc is the use of zinc oxide in the production of most rubber products. According to CANMET (2005), zinc oxide makes up about 1.2% of passenger tyres, which is indeed confirmed by the weighted average concentration of 1.0% (10 463 ppm). Ziram (zinc dimethyldithiocarbamate) is used in the vulcanization of rubber (IARC (1991)). This is confirmed by REACH registrants who identify the use in the manufacture of rubber products. However, around 50 % of manufacturers of Ziram

[45] The substance information marked in red is the information collected or calculated from the worst case harmonised classification of the metal speciation of the relevant metal.
[46] See explanation in Criterion 6.

						weight ratio was 2 L/kg. The concentration range from 9 samples of SBR leachates were [80 – 129 000] µg/L with an average of 15 831 µg/L and median of 1 310 µg/L. **(Kruger et al., 2013)** Measured in water at pH 7.03. Temperature was not reported. The volume to weight ratio was 2 L/kg. The concentration from 1 sample leachate was 3 700 µg/L. **(Bocca, 2009)**[47] Measured in water. No pH was reported. Temperature ~20 °C and volume to weight ratio of 10 L/kg. The median concentration from 5 samples was 966 µg/L. Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 2 300 µg/L and was in the range of [2.0 – 62 120] µg/L. **(Plesser, 2004)** Measured in water at pH [7.80 – 7.54], temperature [26.0 - 27.8] °C and volume to weight ratio of 10 L/kg. The concentration was measured (from 3 samples)	have informed that Ziram is not used in tyres in their supply chain. <u>Conclusion:</u> **Further risk assessment needed.**

[47] Note that the leachates were obtained in a special way. First extract, left in water for 0–24 h, were discarded. The same granulates were treated a second time with fresh water for another 24 h. Only measurements of the second extract were reported.

						to be 1 366 µg/L and in the range of [590 – 2 290] µg/L. **(Gomes et al., 2010)**[48] Measured in water at pH [4-5]. The temperature was not reported. The volume to weight ratio was 10 L/kg. The concentration value reported was 6 900 µg/L. **(DK-EPA, 2008)** Measured in water at pH 4.7. No temperature was reported. The volume to weight ratio was 10 L/kg. The median concentration (from 2 samples) reported was 6 950 µg/L and was in the range of [5 900 – 8 000] µg/L.	
2	4-(1,1,3,3-tetramethylbutyl)phenol (4-tert-octylphenol)	11.5	4.8 - 33.7	10	15	**(Magnusson and Mácsik, 2017)** Measured "Phenol derivatives" from water leachate. No pH was reported. The volume to weight ratio was 10 L/kg. The concentration measured from one sample was 1.4 µg/L from ELT. Measurements from other material was also done such as TPE (1.8 µg/L) and from recycled-EPDM (11 µg/L). These were also measured from one sample each. **(Plesser, 2004)** 4-t-Octylphenol measured at	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 0.1 µg/L. AA-EQS (Annual Average Environmental Quality Standard) values for the substance is 0.1 ug/L for inland surface waters[49]. The leaching measurements, for which the L/S (liquid to solid ratio) was 10, are between 1-5 order of magnitude greater than the $PNEC_{freshwater}$ value. Furthermore, RAC has not concluded on a threshold /non-threshold nature of the endocrine disrupting properties of NPnEO in its opinion on a restriction proposal[50]. Number of samples: The number of samples (10) is considered to be sufficient for risk assessment. Other risk management measures: The ethoxylated versions of this compound is already regulated through the authorisation process (entry 42), but

[48] The number of samples were not reported, and neither was the type of statistical value used (average, median, etc.).
[49] EQS Directive: Inland surface waters encompass rivers and lakes and related artificial or heavily modified water bodies (freshwater)
[50] https://echa.europa.eu/documents/10162/69d460a1-4192-910c-386e-95809b1a5a65

						pH [5.63 -6.35] and at temp C° [20.2 - 21.3]. The water to solid material ratio (L/S) was 10 L/kg. The average concentration from 2 samples of recycled rubber granulate was 3 275 µg/L and the range was between [2950-3600] µg/L.	the non-ethoxylated version (4-tert-octylphenol) is not part of the Annex XIV entry. However, the endpoints for which the ethoxylated versions are being regulated are based on the hazards for this compound (non-ethoxylated 4-tert-octylphenol). The very similar substances nonylphenol and nonylphenol ethoxylates are already restricted for several uses, see annex XVII entry 46 and 46a[51]. However, it is not sufficiently regulated to reduce the risk for the environment from infill material. Possible reason for presence: As cited in the ECHA report (2017), according to ETRMA (expert judgement), 4-tert-octylphenol may be present in rubber granules (0-200 ppm). The (UK-EA, 2005) states that the substance is used in tyres as part of a tackifier resin. The total concentration of octyl-phenol in a typical tyre is estimated to be around 0.3 %. In addition, according to ETRMA, para ter butyl phenol (CAS 98-54-4) may be present in rubber granules (0-100 ppm), this substance is not listed in the main excel table (Annex 1). Conclusion: **Further risk assessment needed.**
3	Cobalt (worst case = Cobalt dichloride)	32.1	3.5 - 268	49	12 (15)	**(RIVM, 2017)[52]** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median concentration was 0.06 mg/kg dry matter and maximum 0.4 mg/kg (average values of each pitch – detected in at least 5 % of the samples). (Corresponding	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance (cobalt) is 0.62 µg/L. The average leaching measurements, for which the L/S (liquid to solid ratio) was 10, the average amount leached is greater than the $PNEC_{freshwater}$. From Bocca (2009) the leaching concentrations measured, with an L/S ratio of 16, were also greater than the $PNEC_{freshwater}$. Topsoil: the concentration in rubber infill is greater than reported for soil (see Annex 2). Other risk management measures: The substance has an RMOA[53] (by the NL) but it is currently on hold. The RMOA is not assessed for environmental

[51] https://echa.europa.eu/documents/10162/b91a8a69-f38e-4a35-ab7d-e475e5926988 and https://echa.europa.eu/documents/10162/7dcd73a4-e80d-47c5-ba0a-a5f4361bf4b1
[52] Information on metals are from 546 samples from 91 pitches.
[53] https://echa.europa.eu/rmoa/-/dislist/details/0b0236e1821a6b99

						concentrations 6 µg/L and 40 µg/L (respectively)). **(Ruffino, 2013)** Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. The average concentration (from 4 samples) reported was 10.71 µg/L and was in the range of [9.03 – 12.5] µg/L. One sample from TPE material was measured with concentration 4.8 µg/L (pH = 7.36). L/S ratio was 10 L/kg and no temperature was measured. **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 1.5 µg/L and was in the range of [<LoQ – 41.0] µg/L.	endpoints. The CLH opinion proposes a concentration limit of 0.01 % for the threshold for classification. The weighted average of the content measurements is below this limit (32 ppm = 0.0032 %). Five soluble cobalt salts are proposed to be restricted due to human health concerns. Number of samples: The number of samples (49) is considered to be sufficient for risk assessment. Possible reason for presence: Probable main reason for presence is that several cobalt compounds are used as metal bonding agents (they react creating links with polymers or brass coating of coated steel cords) (ETRMA (2018); (Miracema-Nuodex, 2018); Noordermeer (2018)). Other contributions are residue of catalyst for the polymerisation of polybutadiene (BR) (Noordermeer (2018); ETRMA (2018)). Cobalt dichloride may be used as catalyst. Conclusion: **Further risk assessment needed.**
4	Lead	26.4	0.7 - 308	60	15	**(RIVM, 2017)**[54] Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ for lead from the registration dossier is 2.4 µg/L and the AA-EQS value for inland surface waters under the WFD is 1.2 µg/L (bioavailable concentration). The maximum leachate concentration, for which the L/S (liquid to solid ratio) was 10, is greater than the unadjusted WFD EQS value and the $PNEC_{freshwater}$. Bocca (2009)

[54] Information on metals are from 546 samples from 91 pitches.

						concentration was <LOD mg/kg dry matter and maximum 0.1 mg/kg (average values of each pitch – detected in fewer than 5 % of the samples). (Maximum concentration corresponding 10 µg/L). **(Ruffino, 2013)** Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. The concentrations (from 4 samples) reported were all below the LoD [4.2 µg/L]. **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 1.6 µg/L and was in the range of [<LoQ – 27] µg/L. **(Gomes et al., 2010)**[55] Measured in water at pH [4-5]. The temperature was not reported. The volume to weight ratio was 10 L/kg. The concentration value reported was 3 µg/L.	and Gomes et al. (2010) also report leachate concentrations greater than the $PNEC_{freshwater}$ and the unadjusted EQS. The LoD for the Ruffico (2013) study is above the aquatic threshold values. <u>Topsoil:</u> The $PNEC_{soil}$ from the registration dossier for the substance is 212 mg/kg soil dw. The weighted average of the concentration measurements in infill materials is lower than the $PNEC_{soil}$ value, but the maximum value above. The average concentration in rubber infill is slightly greater than the average reported for soil (see Annex 2). The maximum concentration in infill material is within the range of topsoil concentrations (<3-886 mg Pb/kg soil). <u>Number of samples:</u> The number of samples (60) is considered to be sufficient for risk assessment. <u>Other risk management measures:</u> Restriction on lead in jewellery articles and articles supplied to the general public (entry 63 of Annex XVII to REACH). The same entry was amended in 2021 to cover also lead in gunshot in or around wetlands. In addition, ECHA has proposed a restriction on the placing on the market and use of lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities. <u>Possible reason for presence:</u> Impurity in tyres. Potentially present in zinc oxide. It reacts creating links with polymers and / or other vulcanization agents. <u>Conclusion:</u> **Further risk assessment needed.**

[55] The number of samples were not reported, and neither was the type of statistical value used (average, median, etc.).

5	4,4'-isopropylidenediphenol (BPA)	0.5	Minimum not reported - 2.5	7	14	*No information on the substance leaching from rubber infill material was found.*	Comparison of content measurements to key soil values: The $PNEC_{soil}$ from the registration dossier for the substance is 3.7 mg/kg soil dw. The weighted average (as well as the maximum reported value of 2.5 mg/kg) of the concentration measurements in infill materials are lower than the $PNEC_{soil}$ value. Nevertheless, the substance has been identified as SVHC due to endocrine disrupting properties (environment and human health). According to the background document adopted by ECHA's Member State Committee 'based on the current data and knowledge it appears difficult to derive and quantify a safe level of exposure for BPA, although it might exist. Effects on non-traditional endpoints and in specific species occurred at lower concentrations than those considered by standard OECD test guidelines.'[56] Number of samples: The number of samples (7) is considered to be sufficient for risk assessment. Other risk management measures: Restriction on BPA (entry 66)[57], but only for thermal paper. Not included in HH risk assessment for rubber infill material. Possible reason for presence: Probable main reason for presence is its properties as an antioxidant ((R. Aabøe, 2002)). Conclusion: **Further risk assessment needed.**
6	N-1-naphthylaniline (PANA)	106	NA only measured in one rubber infill sample (out of 5) in DK EPA (2008)	1	14	*No information on the substance leaching from rubber infill material was found.*	Comparison of content measurements to key soil values: The $PNEC_{soil}$ from the registration dossier for the substance is 0.007 mg/kg soil dw. The weighted average of the content measurements in infill materials is substantially greater (five orders of magnitude) than the $PNEC_{soil}$ value.

56 https://echa.europa.eu/documents/10162/769b2777-19cd-9fff-33c4-54fe6d8290d5
57 https://echa.europa.eu/documents/10162/370b5de7-9507-f1b4-edc6-80ef2e5cd781

							Number of samples: The number of samples (1) would create large uncertainties and is not considered sufficient for risk assessment. Other risk management measures: Under consideration as a PBT/vPvB (Dossier by German MSCA[58]). Covered by the HH risk assessment for rubber infill material. Could be sufficient for environmental management as well. Possible reason for presence: As cited in the ECHA report (2017),according to ETRMA (expert judgement), aniline is used as anti-aging agent and antidegradants. Aniline (CAS 62-53-3) (not the current substance) may be present in rubber granules (0-100 ppm). Possible main reason for presence: according to REACH registrants N-1-naphthylaniline is used for the manufacture of rubber products. Conclusion: **Candidate for further risk assessment, but not enough data to currently do further risk assessment (uncertainty regarding the typical concentration data).**
7	Chromium (worst case = Chromium trioxide)	5.4	0.3 - 56	59	4 (13)	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median concentration was <LOD mg/kg dry matter and maximum 0.02 mg/kg (average values of each pitch – detected in fewer than 5 % of the samples). (Maximum concentration corresponding 2 µg/L). **(Ruffino, 2013)**	Elemental chromium does not score points for any environmental hazard criteria. Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance (chromium) is 6.5 µg/L. For all medians/averages of leaching measurements the values are lower than the $PNEC_{freshwater}$. The one value from literature that is over the $PNEC_{freshwater}$ is the maximum leaching value (leached into acetic acid) reported from Bocca (2009). Topsoil: The weighted average concentration of chromium in rubber infill is 5 mg Cr/kg infill (range of 0.3 – 56 mg Cr/kg infill). Levels in soil are on average 22 mg Cr/kg (range of 2-274 mg Cr/kg). Based on this information the concentration of chromium in infill is well below that in topsoil.

[58] https://echa.europa.eu/pbt/-/dislist/details/0b0236e1809fe509

						Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. No chromium was detected as all measurements from 4 samples were below LoD (< 0.71 µg/L). **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 0.90 µg/L and was in the range of [0.20 – 10.0] µg/L. **(Gomes et al., 2010)**[59] Measured in water at pH [4-5]. The temperature was not reported. The volume to weight ratio was 10 L/kg. The concentration value reported was 3 µg/L.	Number of samples: The number of samples (59) is considered to be sufficient for risk assessment. Other risk management measures: Covered by the HH risk assessment for rubber infill material. Could be sufficient for environmental management as well. Possible reason for presence: Elemental chromium could be present due to compound contact with stainless steel during tyre and/or crumb production (ETRMA 2018). Possible impurity in zinc oxide used for the sulphur-vulcanization of tyre elastomers (Noordermeer (2018)). Possible impurity in steel (CANMET (2005)). Since the source of chromium and the speciation is not currently clear, it cannot be excluded that some limited fraction of the total chromium is present as hexavalent chromium. In one study Cr VI was specifically reported but the concentration was below LOD or LOQ (specified as <0.004 mg/kg in ESTO (2016)). Conclusion: **No need for further risk assessment.**
8	N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine	805	649 - 1039	3	13	**(DK-EPA, 2008)** Measured in water. No temperature or pH was reported. The volume to weight ratio was 10 L/kg. Measured from 3 samples from ELT granulates the average concentration was 550.67 µg/L and the measurements ranged from [324 - 687] µg/L.	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 0.37 µg/L. The leaching concentrations are greater than (three orders of magnitude) the $PNEC_{freshwater}$. Number of samples: The number of samples (3) is low and would introduce significant uncertainty to any risk assessment. Other risk management measures: Was reviewed for possible PBT/vPvB properties and it does not meet the P criterion. Does meet screening criteria

[59] The number of samples were not reported, and neither was the type of statistical value used (average, median, etc.).

							for B and T[60]. Not covered by the HH risk assessment on infill material. Possible reason for presence: As cited in the ECHA report (2017), according to ETRMA (expert judgement) phenylenediamine compounds are used as antiaging agents and antidegradants. , N-1,3 dimethylbutyl N´phenyl-p-phenyldiamine (CAS 793-24-8) may be present in rubber granules (0 - 1 000 ppm). No harmonised classification, but registrants has reported the following environmental concerns: Aquatic Acute 1, Aquatic Chronic 1. Conclusion: **Candidate for further risk assessment, but not enough data to currently do further risk assessment (uncertainty regarding the typical concentration data).**
9	Bis(2-ethylhexyl) phthalate (DEHP)	7.8	7.6 -– 52	550	12	**(DK-EPA, 2008)** Measured in water. No temperature or pH was reported. The volume to weight ratio was 10 L/kg. Measured in 1 sample from ELT granulates. Concentration was 14 µg/L. **Plesser (2004)** Measured at pH 7.7 and at temp C° [28.0 - 28.4]. The water to solid material ratio (L/S) was 10 L/kg. The average concentration from 2 samples of recycled rubber granulate was 5.35 µg/L and the range was between [5.1 – 5.6] µg/L.	Comparison of leaching measurements to key water values: From the registration dossiers no PNECs has been derived for water as no hazard for the environment has been identified. The WFD derived an AA-EQS value for inland surface waters of 1.3 µg/L. Leaching measurements for the substance are 5-14 times greater than the EQS value. In addition, the substance has been identified as SVHC due to the endocrine disruption properties (environment and human health). According to the background document adopted by ECHA's Member State Committee 'no toxicological threshold for the endocrine disruption caused reproductive toxic effects has yet been scientifically proposed, discussed and concluded and/or agreed for DEHP.'[61] Number of samples: The number of samples (550) is considered to be sufficient for risk assessment. Other risk management measures: Listed on Annex XIV[62] However, some potential risk to the environment from authorised uses. Restriction only

[60] https://echa.europa.eu/documents/10162/4c7e5dc7-cf94-44a9-8968-61cec26f3575
[61] https://echa.europa.eu/documents/10162/fa429d23-21e7-4764-b223-6c8c98f8a01c
[62] https://echa.europa.eu/authorisation-list/-/dislist/details/0b0236e1807e0026

							covers articles containing >0.1 %[63]. Possible reason for presence: ECHA report (2017): ETRMA provided information, that even though non-reactive substances, like plasticisers are used in the production of tyres, no phthalates are used.[64][65] Conclusion: **Further risk assessment needed.**
10	Arsenic	0.8	0.1 - 5.3	52	12	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram rubber granulate. The concentrations were below the LOD. **(Ruffino, 2013)** Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. No arsenic was detected as all measurements from 4 samples were below LoD (< 5.3 µg/L). **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 13 µg/L. The leaching concentrations are lower than the $PNEC_{freshwater}$. Topsoil: the concentration in rubber infill is similar or lower than in soil (see Annex 2). The concentration in rubber infill (weighted average) is lower than the average concentration in topsoil. Also, the maximum concentration in rubber infill is similar to the average concentration in topsoil and well within the range of topsoil concentrations. Number of samples: The number of samples (52) is considered to be sufficient for risk assessment. Other risk management measures: Restriction in place (entry 19 of Annex XVII to REACH) but not covering rubber infill material[66]. Not covered in HH risk assessment for rubber infill material. Possible reason for presence: no explanation for the presence of arsenic in rubber crumb was found. Conclusion: **No need for further risk assessment.**

[63] https://echa.europa.eu/documents/10162/aaa92146-a005-1dc2-debe-93c80b57c5ee
[64] Specific oils (e.g. TDAE (Treated Distillate Aromatic Extract), MES (Mild Extracted Solvate, RAE (Residual Aromatic Extract) and naphtenic oils can be used in rubber to give plasticising effect.
[65] DEHP may be used in some rubber parts of articles (see requests under ROHS): https://rohs.exemptions.oeko.info/index.php?id=288. It is not known if they are used as a raw materials for infills or if DEHP is due to legacy use of phthalates in tyres.
[66] https://echa.europa.eu/documents/10162/a798c758-371f-41e5-a38d-5f8dc9ba739d

						samples was 0.12 µg/L and was in the range of [<1 (LoQ) – 2.4] µg/L.	
11	Barium	245.4	2.4 - 4778	49	12	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median concentration was <0.05 mg/kg dry matter and maximum 0.2 mg/kg (average values of each pitch – detected in at least 5 % of the samples). (Concentrations corresponding < 5 µg/L and 20 µg/L (respectively)). **(Ruffino, 2013)** Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. The average concentration (from 4 samples) reported was 15 µg/L and was in the range of [10.9 – 21.3] µg/L. **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 114.7 µg/L. The average and median leaching concentrations from the leaching studies are lower than the $PNEC_{freshwater}$. However, there is one maximum value from Bocca (2009) (2 050 µg/L) which exceeds the PNEC value. Topsoil: the concentration in rubber infill is not lower than in soil (see Annex 2). However, the weighted average concentration in rubber infill (245.4 mg Ba/kg infill) is still within the concentration range in topsoil (10 – 1700 mg Ba/kg soil). Number of samples: The number of samples (49) is considered to be sufficient for risk assessment. Other risk management measures: Not covered by any risk management measures at the moment. Not covered by the HH risk assessment for infill material. Possible reason for presence: Limited information available. Compounds containing barium have a variety of commercial uses. Barium sulfate, or barite (BaSO4), is reported to be used as a filler in the automotive industry and rubber[67]. Conclusion: **No need for further risk assessment.**

[67] https://www.barytes.org/uses/

						concentration from 32 samples was 27 µg/L and was in the range of [2.00 – 2050] µg/L.	
12	Cadmium	0.7	0.11 - 3	60	12	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and at room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The concentrations were below LOD. **(Ruffino, 2013)** Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. No cadmium was detected as all measurements from 4 samples were below LoD (< 0.25 µg/L). **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 0.20 µg/L and was in the range of [<0.01 – 0.7] µg/L.	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 0.19 µg/L. The median leaching concentration (0.20 µg/L) from 32 samples from Bocca (2009) is within the same order of magnitude as the $PNEC_{freshwater}$. Topsoil: the concentration in rubber infill is not lower than that in topsoil (see Annex 2). The weighted average concentration in rubber infill (0.7 mg Cd/kg infill) is greater than the average concentration in topsoil (0.09 and 0.28 mg Cd/kg soil). The maximum concentration in rubber infill is within the range of reported concentrations in topsoil, although these samples may represent polluted soils. Number of samples: The number of samples (60) is considered to be sufficient for risk assessment. Other risk management measures: Restriction on cadmium in plastics (entry 23 of Annex XVII to REACH) only covers certain material[68]. EPDM, BPR or TPE are not part of that list. Not covered by the HH risk assessment on infill material. Possible reason for presence: Possible impurity in zinc oxide used for the sulphur-vulcanization of tyre elastomers (Noordermeer (2018)). Conclusion: **Further risk assessment needed.**

[68] https://echa.europa.eu/documents/10162/3bfef8a3-8c97-4d85-ae0b-ac6827de49a9

13	Copper	19.8	0.8 - 111	60	12	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median concentration was 0.09 mg/kg dry matter and maximum 0.9 mg/kg (average values of each pitch – detected in at least 5 % of the samples). (Corresponding concentrations 9 µg/L and 90 µg/L (respectively)). **(Ruffino, 2013)** Measured in deionized water at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. The average concentration (from 4 samples) reported was 13.9 µg/L and was in the range of [6.62 – 22.1] µg/L. **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 2.20 µg/L and was in the range of [0.2 – 216] µg/L.	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ for copper from the registration dossier is 7.8 µg/L. The $PNEC_{marine}$ is reported as 5.2 µg/L. The median and maximum leachate concentration, for which the L/S (liquid to solid ratio) was 10, is greater than the $PNEC_{freshwater}$ and $PNEC_{marine}$. Ruffino (2013) and Bocca (2009) report leachate concentrations greater than the $PNEC_{freshwater}$ and $PNEC_{mariner}$. Topsoil: The $PNEC_{soil}$ from the registration dossier for the substance is 65 mg/kg soil dw. The weighted average of the concentration measurements in infill materials is lower than the $PNEC_{soil}$ value, but the maximum value is above. The average concentration in rubber infill is slightly greater than the average reported for soil (see Annex 2). The maximum concentration in infill is within the range of topsoil concentrations (1-239 mg Cu/kg soil). Number of samples: The number of samples (60) is considered to be sufficient for risk assessment. Other risk management measures: No specific regulatory measures under REACH. Copper flakes (coated with aliphatic acid) have been approved for use as an antifouling product under the Biocide Product Regulation ((EU) No 528/2012). Some other applications under the Biocide Regulation are under consideration. Possible reason for presence: Used as steel strips, cords included in tyres. Conclusion: **Further risk assessment needed.**
14	Vanadium (worst case = divanadium pentaoxide)	3.3	0.4-22	44	8 (11)	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 7.6 µg/L. All leaching values are below the PNEC value except a maximum measurement which is 1.5 times greater than the

						10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The concentrations were below LOD. **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 0.94 µg/L and was in the range of [0.14 – 11.0] µg/L.	PNEC value for freshwater. <u>Topsoil</u>: the concentration in rubber infill is lower than that in topsoil (see Annex 2). The weighted average concentration of vanadium in rubber infill is 3 mg V/kg infill (range of 0.4-22 mg V/kg infill). Levels in soil are on average 38 mg V/kg (range of 1-281 mg V/kg). Based on this information the concentration of vanadium in infill is well below that in topsoil. <u>Number of samples:</u> The number of samples (44) is considered to be sufficient for risk assessment. <u>Other risk management measures:</u> No risk management measures in place. Covered by the HH risk assessment. <u>Possible reason for presence:</u> White sidewalls based on EPDM-rubber (very uncommon in the EU) could contain traces of vanadium as catalysts residues (Noordermeer, 2018). <u>Conclusion:</u> **No need for further risk assessment needed.**
15	Manganese (worst case = Maneb)	5.3	0.14 - 30	49	8 (11)	**(RIVM, 2017)** Measured in (filtered) water at pH approximately 7 and room temperature. The volume to weight ratio was 10 L/kg. Amounts were expressed in mg of leachate per kilogram of rubber granulate. The median concentration was 0.11 mg/kg dry matter and maximum 0.96 mg/kg (countercheck study – 42 samples from 7 pitches). (Corresponding concentrations 11 µg/L and 96 µg/L (respectively)). **(Ruffino, 2013)** Measured in deionized water	<u>Comparison of leaching measurements to key water values:</u> The $PNEC_{freshwater}$ from the registration dossier for the substance is 34 µg/L. Average leachate concentration in deionised water (L/S ratio of 10) of 26.85 µg/L with a reported range of 12.3 to 42.4 µg/L. The maximum values from RIVM (2017) and Ruffino (2009) were greater than the PNEC. <u>Topsoil</u>: the concentration in rubber infill is lower than that in topsoil (see Annex 2). The weighted average concentration in rubber infill is 5.3 mg Mn/kg infill (range of 0.14-30 mg Mn/kg infill). Levels in soil are on average 373 mg Mn/kg soil (range of 9.6 – 2 285 mg Mn/kg). Based on this information the concentration of manganese in infill is well below that in topsoil. <u>Number of samples:</u> The number of samples (49) is considered to be sufficient for risk assessment.

						at pH 6.54 (average), ranging between [6.41 – 6.51]. No temperature was reported. The volume to weight ratio was 10 L/kg. The average concentration (from 4 samples) reported was 26.85 µg/L and was in the range of [12.3 – 42.4] µg/L. **(Bocca, 2009)** Measured in acetic acid at pH 5, temperature 25 °C and volume to weight ratio of 16 L/kg. The median concentration from 32 samples was 33.0 µg/L and was in the range of [7.00 – 220] µg/L.	Other risk management measures: No risk management measures in place. Not covered by the HH risk assessment for infill material. Possible reason for presence: Bead wire contains around 0.5% manganese(VERT, 2018). Manganese could be present in some fillers (ETRMA, 2018). Maneb and other dithiocarbamates (e.g. Ziram) are used in rubber production as sulfur donors (vulcanising agents and accelerators).[69] Tire rubber has been found to adsorb pesticides such as maneb, Park and Ye (2016). However, it would be in very special cases where the rubber has come in contact with this specific type of fungicide. It would neither constitute the major portion of manganese found in rubber infill material. Conclusion: **No need for further risk assessment.**
16	Benzyl butyl phthalate (BBP)	0.8	Minimum not reported - 2.8	8	11	**(DK-EPA, 2008)** Measured in water. No temperature or pH was reported. The volume to weight ratio was 10 L/kg. Measured in 1 sample from ELT granulates. Concentration was 43 µg/L.	Comparison of leaching measurements to key water values: The $PNEC_{freshwater}$ from the registration dossier for the substance is 7.5 µg/L. The leaching measurement exceeds the PNEC (6 times greater). Number of samples: The number of samples (8) is considered to be sufficient for risk assessment. Other risk management measures: Part of authorisation list[70] (Endpoint is toxic for reproduction (57c)). Still some potential risk to the environment even from authorised uses. Restriction entry 51 of Annex XVII to REACH only covers articles containing 0.1 %[71], however the weighted average of the content measurements is below that limit 0.000075 % (0.75 ppm = 0.000075 %). Could be an environmental risk not managed by the

[69] https://books.google.fi/books?id=BgmkCgAAQBAJ&pg=PA161&lpg=PA161&dq=Dithiocarbamates+Maneb+rubber+production+mangan-ethylene-bisdithiocarbamate&source=bl&ots=0wzkeTzogn&sig=Ueox6hdFVDBJ9S_XacdfM1h7D70&hl=en&sa=X&ved=2ahUKEwi71ZOZi9PdAhVxhaYKHZ2UBtYQ6AEwAHoECAAQAQ#v=onepage&q=Dithiocarbamates%20Maneb%20rubber%20production%20mangan-ethylene-bisdithiocarbamate&f=false
[70] https://echa.europa.eu/authorisation-list/-/dislist/details/0b0236e1807dff4e
[71] https://echa.europa.eu/documents/10162/aaa92146-a005-1dc2-debe-93c80b57c5ee

							regulations in place. Not covered by the HH risk assessment for infill material. Possible reason for presence: ECHA report (2017): ETRMA provided information, that even though non-reactive substances, like plasticisers are used in the production of tyres, no phthalates are used. Conclusion: **Further risk assessment needed.**
17	Benzothiazole-2-thiol	2.6	Minimum not reported - 7.6	7	11	*No information on the substance leaching from rubber infill material was found.*	Comparison of content measurements to key soil values: The $PNEC_{soil}$ from the registration dossier for the substance is 0.027 mg/kg soil dw. The weighted average of the content measurements in infill materials is higher (~2 orders of magnitude) than the $PNEC_{soil}$ value. Number of samples: The number of samples (7) is considered to be sufficient for risk assessment. Other risk management measures: Has a harmonised classification[72] for Aquatic Acute 1 and Aquatic Chronic 1, but no specific concentration limit. Not covered by the HH risk assessment for infill material. Possible reason for presence: ECHA report (2017): ETRMA provided information on categories of substances used in the production of tyres and substances which may possibly be present in ELT-derived rubber granules (expert judgement). According to ETRMA, benzothiazole compounds are used as vulcanisation agents. Mercapto benzothiazole (benzothiazole-2-thiol) (CAS 149-30-4) may be present in rubber granules (0-200 ppm). Used as accelerator for vulcanization of rubber[73]. Conclusion: **Further risk assessment needed.**
18	Dodecyldimethylamine	125	Only measured in one	1	10	*No information on the substance leaching from*	Comparison of content measurements to key soil values:

[72] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/77605
[73] http://dynasolgroup.com/product/rubator-mbt/

			sample (Nilsson et al 2008)			*rubber infill material was found.*	The $PNEC_{soil}$ from the registration dossier for the substance is 1 mg/kg soil dw. The weighted average of the content measurements in infill materials is higher (~2 orders of magnitude) than the $PNEC_{soil}$ value. Number of samples: The number of samples (1) would create large uncertainties and is not considered sufficient for reliable risk assessment. Other risk management measures: No risk management measures in place. Not covered by the HH risk assessment for infill material. Possible reason for presence: No reason found for the presence of the substances in tyres. Conclusion: **A candidate for further risk assessment, but not enough sample data to currently do further risk assessment (uncertainty regarding the typical concentration data).**

5. Discussion and conclusions

ECHA's prioritisation approach identified substances which were then subject to further screening and preliminary assessment. The prioritisation was carried out in order to identify relevant substances from the initial list of substances, i.e. list of substances which were reported to be connected in different ways to the infill material. The prioritisation criteria were developed for this purpose by ECHA. In addition to hazardous properties of the substances, the criteria included exposure/emission criteria, which focuses whether a substance had been measured in infill material in available studies. This may give somewhat biased results, but as exposure/emission information is needed for a risk assessment, inclusion of this criteria was considered essential. Any new information on emissions and exposure should be taken into account in any further assessments.

The origin of the substances detected in rubber crumb infill are mainly from end-of-life tyres (ELT) and in some cases from other recycled rubber material. As an example, phthalates are not used as plasticisers in tyres (ETRMA, 2017 as referred in ECHA, 2017), thus the origin of those substances may be from other recycled rubber articles. This issue can be further investigated in any future assessments.

5.1. Human health

On 2 November 2018, ECHA sent to the Commission a paper outlining the approach and results of the prioritisation of substances in infill material for further human health risk assessment. The outcome of the prioritisation was that 12 candidate substances were selected for further human health risk assessment.

A preliminary human health risk assessment of the 12 substances followed. ECHA concludes that the risks from exposure to chromium (Cr), nickel (Ni), selenium (Se), beryllium (Be), magnesium (Mg), vanadium (V), lithium (Li) and mercury (Hg) from playing on pitches with artificial rubber infill can be considered negligible. No further human health risk assessment on these metals will be undertaken.

A robust human health risk assessment for PANA and NMP cannot currently be carried out because their typical concentration in rubber infill is not known. Nevertheless, considering the threshold mode of action of systemic effects for these substances and that the limited available data indicates that concentrations in rubber infill are low (0.01% and 0.008%), these substances are considered to be a low priority for risk management.

The preliminary human health risk assessment does not exclude a potential concern for cobalt and zinc in infill. Further risk assessment for cobalt and zinc is needed to establish whether there is a risk for human health from their presence in rubber infill that is not adequately controlled.

5.2. Environment

In the initial list of identified substances there were several (non dioxin-like) PCBs, but they were not prioritised. As stated in RIVM (2017), the total concentration of the seven different PCBs is above the soil limit for residential classification in the Netherlands (0.04 mg/kg). Therefore, ECHA proposes that in any future assessments as regards environmental risks of infill materials, relevant combined or mixture effects of substances should be considered.

Based on the risk screening of prioritised substances, ECHA concludes that there is a need to further assess the risks to the environment of the following substances found in infill material: cadmium, cobalt, copper, lead, zinc, 4-tert-octylphenol, 4,4´-isopropylidene diphenol (BPA), bis(2-ethylhexyl)phthalate (DEHP), benzyl butyl phthalate (BBP) and benzothiazole-2-thiol.

5.3. Overall conclusion

There is a potential concern for human health and the environment on certain substances in infill material used on synthetic turf pitches. Further work is recommended to be done within the context of an Annex XV restriction proposal. Any further work should include an assessment of recently published studies that were not considered as part of this assessment. Similarly, a new search of registration dossiers for substances used in the production of tyres would need to be conductedt. These sources may identify additional substances for risk assessment.[74]

It is important to note that alongside this assessment ECHA has, at the request of the Commission, proposed a restriction on intentionally added microplastics, that includes within its scope the plastic and rubber infill used on synthetic turf pitches. The decision by the Commission and the Member States on the implementation of the proposed microplastics restriction (i.e. whether and under which timescale a ban on the use of microplastics as infill on synthetic pitches was required) would affect the need for risk management for the substances identified in this report, potentially making any further risk management unnecessary.

[74] Examples of new studies not reviewed yet: https://science.sciencemag.org/content/371/6525/185 and https://reader.elsevier.com/reader/sd/pii/S0048969720306847?token=6B8E6DF71D265BB3A30B3A040DE398F18BBBBDE67AE302BE025A79D16D8550322E1C14714A61711184F8ABA968901B5A&originRegion=eu-west-1&originCreation=20210419075045 (including Part 2 and Part 3 of the study).

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Annex 1 Full list of substances with scoring

See excel sheet 1 with file name “Rubber infill HH prioritisation scores” published separately.

See excel sheet 2 with file name “Rubber infill ENV prioritisation scores” published separately.

Annex 2 Comparison of concentrations of metals in topsoil and in rubber infill

Metal	**Concentration in rubber infill** **(mg/kg)**	**Concentration in topsoil** **(mg/kg)** (EU, unless specified otherwise)	**Is concentration in rubber infill similar or lower than in soil?**
Co	weighted average: 32 range: 4 – 268	average: 6 range : 0.3-92 (Tóth et al. (2016))	No
Cr	weighted average: 5 range: 0.3-56	average: 22 range : 2-274 (Tóth et al. (2016))	Yes
Cu	weighted average: 19.8 range: 0.8 - 111	average : 16 range : 1-239 (FOREGS (2005))	No/borderline
Ni	weighted average: 3 range: 0.6-26	average: 18 range : 0.4-466 (Tóth et al. (2016))	Yes
Pb	weighted average: 26.4 range: 0.7 - 308	average : 24 range : <3-886 (FOREGS (2005))	No/borderline
Zn	weighted average: 10 500 range: 118 – 21 000	average: 61 range : 4-2270 (FOREGS (2005))	No
Se	weighted average: 0.4 range: 0-3.2	median, UK : 0.5 (UKSO (2018))	Yes
Be	weighted average: 0.1 range: 0.001 – 0.37	median : <2 range : <2-18 (FOREGS (2005))	Yes
Mg	weighted average: 448 range: 123 - 966	average: 12 000 range : <100-250 000 (FOREGS (2005))	Yes
V	weighted average: 3 range: 0.4-22	average: 38 range : 1-281 (FOREGS (2005))	Yes
Li	weighted average: 2 range: 0.6-11	average: ca. 11.4 Agricultural and	Yes

		grazing soil Negrel et al. (2017)	
Hg	weighted average: 0.1 range: 0.03 – 3	average: 0.04 range : 0-1.6 (Tóth et al. (2016)) average: 0.06 range : 0.005-1.4 (FOREGS (2005)) median: 0.03 range: <0.003–1.6 (agricultural soil) median: 0.04 range: <0.003–3.1 (grazing soil) (Ottesen et al. (2013))	No/borderline

ECHA compared the concentrations of the prioritised metal substances in rubber infill with typical levels in topsoil. For 7 of the metals that were among the candidate substances for further human health risk assessment the concentrations were similar or lower than to those found in topsoil. These metals are chromium (Cr), nickel (Ni), selenium (Se), beryllium (Be), magnesium (Mg), vanadium (V) and lithium (Li). When concentrations of metals in rubber infill are similar or lower than typical levels in soil used in natural grass pitches, and in the absence of information that the toxicity of the species and its bioaccessibility in rubber infill would be significantly higher, the risks from exposure to these metals from playing on these pitches can be considered negligible. See Annex 2 and the following discussion. Furthermore, ECHA compared the concentrations with the limit values in Toy Safety Directive (Annex 3), see below the discussions.

5.3.1.1. Chromium

The weighted average concentration of chromium in rubber infill is 5 mg Cr/kg infill (range of 0.3 – 56 mg Cr/kg infill). Levels in soil are on average 22 mg Cr/kg (range of 2-274 mg Cr/kg). Based on this information the concentration of chromium in infill is well below that in topsoil. The source of chromium in infill material and the speciation of chromium is not fully clear. However, chromium could be present due to impact with stainless steel during tyre and/or crumb production, as a possible impurity in zinc oxide used for the sulphur-vulcanization of tyre elastomers, or as a possible impurity in steel that is used in tyres. The concentration of hexavalent chromium was in one study reported to be below 0.004 mg/kg, which is well below the migration limit of 0.02 mg/kg in the Toys Directive (see Annex 3).

5.3.1.2. Nickel

The available information suggests that nickel is mainly present in rubber infill as elemental nickel, as a result of the stainless steel used in tyres (steel strips coated with brass and cords). Stainless steel is rich in nickel. Another minor contribution may be as residue of Ziegler-Natta catalyst for the polymerisation of polybutadiene (BR). Elemental nickel is considered to be a skin sensitiser, carcinogen cat. 2 and repeated dose toxicant. ECHA has no evidence that the substance nickel dichloride[75] that lead to the prioritisation of nickel is used in rubber infill. The weighted average concentration of nickel in rubber infill is 3 mg Ni/kg infill (range of 0.6-26 mg Ni/kg infill). Levels in soil are on average 18 mg Ni/kg (range of 0.4-466 mg Ni/kg). Based on this information the concentration of nickel in infill is well below that in topsoil. A limited

[75] Carc. 1A, Muta. 2, Repr. 1B, STOT RE 1, Resp. Sens. 1, Skin Sens. 1

amount of the total nickel in soil may be present as non-exchangeable nickel, i.e. as part of clay minerals[76], but in this comparison it should be noted that (some of the) non-exchangeable ions in the crystal lattice may be extracted under acidic environments (such as the stomach) and that metals in rubber infill are not likely to be fully bioaccessible either.

5.3.1.3. Selenium

Selenium is reportedly used as a vulcanising agent and to make rubber more durable. The weighted average concentration of selenium in rubber infill is 0.4 mg Se/kg infill (range of 0-3.2 mg Se/kg infill). Median levels in soil are 0.5 mg Se/kg. Based on this information the concentration of selenium in infill is similar to that in topsoil.

5.3.1.4. Beryllium

No specific information is available for the presence of Be in rubber infill. The weighted average concentration of beryllium in rubber infill is 0.1 mg Be/kg infill (range of 0.001 – 0.37 mg Be/kg infill). Median levels in soil are <2 mg Be/kg (range of <2-18 mg Be/kg). Based on this information the concentration of beryllium in infill is similar to that in topsoil.

5.3.1.5. Magnesium

Hydrated magnesium silicate (talc) is used as a filler in rubber and does not present any risk (and is in fact a clay mineral). Magnesium oxide is reportedly used as a vulcanisation agent, however, it is not REACH registered which makes it unlikely to be an important source for magnesium in rubber infill. Other possible contributions are the use of $MgCl_2$ (REACH registered but no hazards have been classified) or $MgBr_2$ (REACH registered but no hazards other than irritation have been classified) in tyre inner liners. ECHA has no reason to believe that the substance magnesium bis((R)-2-(2,4-dichlorophenoxy)propionate) (EC No 413-360-2) that lead to the prioritisation of magnesium is used in rubber infill. The weighted average concentration of magnesium in rubber infill is 448 mg Mg/kg infill (range of 123 – 966 mg Mg/kg infill). Levels in soil are on average 12 000 mg Mg/kg (range of <100-250 000 mg Mg/kg). Based on this information the concentration of magnesium in infill is far below that in topsoil. Except when magnesium in rubber infill is in the form of hydrated magnesium silicate (talc, itself a clay mineral), the form and bioaccessibility of a sizable fraction of the magnesium in rubber infill may be different from that in soil where magnesium can be to a large extent non-exchangeable magnesium (i.e. it is part of clay minerals such as illite, montmorillonite, talc, sepiolite) in addition to an exchangeable fraction of Mg and a fraction of Mg in solution in the soil water content. However, also non-exchangeable ions in the crystal lattice may be extracted under acidic environments (such as the stomach) and metals in rubber infill are not likely to be fully bioaccessible either. Overall, the magnesium species known to be used in rubber infill are not hazardous and concentrations of metals in rubber infill are far below the typical levels in soil. There are no indications that a risk could be associated with exposure to magnesium in rubber infill.

5.3.1.6. Vanadium

Vanadium may be present as a residue from the use of Ziegler Natta catalysts in rubber production[77]. The weighted average concentration of vanadium in rubber infill is 3 mg V/kg infill (range of 0.4-22 mg V/kg infill). Levels in soil are on average 38 mg V/kg (range of 1-281 mg V/kg). Based on this information the concentration of vanadium in infill is well below that in topsoil.

5.3.1.7. Lithium

Lithium may be present in rubber infill as a residue of butyllithium (EC No 203-698-7, registered) used as a catalyst in rubber production or as additive used by polymers producers.

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[76] https://www.britannica.com/science/clay-mineral

[77] https://www.albemarle.com/businesses/lithium/markets--applications/rubber--plastics

Lithium will not be present as butyllithium in rubber infill as it is highly reactive. The weighted average concentration of lithium in rubber infill is 2 mg Li/kg infill (range of 0.6-11 mg Li/kg infill). Levels in agricultural and grazing soil are on average about 11.4 mg Li/kg. Based on this information the concentration of lithium in infill is well below that in topsoil.

Annex 3 Comparison of the concentrations with limits in the Toy Safety Directive

As a preliminary indication of possible risk from the prioritised substances in rubber infill material a comparison of concentrations of prioritised substances in infill was made with the applicable limits in the Toy Safety Directive[78]. The comparison is presented in Table A 3.1. However, not all prioritised substances have limit values in the Toy Safety Directive.

Without prejudice to the provisions on the CMRs in toys, migration limits apply for elements (metals) listed in point 13 of part III of Annex II of the Toy Safety Directive. The migration limit values are different depending on the material of the toy or the component in question. The categories of material are:

- Dry, brittle, powder-like or pliable toy material; This migration limit assumes 100 mg ingestion of toys such as chalk crayon or modelling clay, a frequency of 1/week and a body weight of 7.5 kg.
- Liquid or sticky toy material; This migration limit assumes ingestion of 400 mg per day of toys such as finger paints, bubble solution, and glue.
- Scraped-off toy material; Solid toy material with or without a coating which can be ingested as a result of biting, tooth scraping, sucking or licking (e.g., paints, polymers, leather, wood, textiles). The assumed ingestion is 8 mg per day.

If rubber infill material would be a toy, then the limit that would be applicable is considered to be the one for category “dry, brittle, powder-like or pliable toy material” and thus the limit corresponding to this category was used in the current comparison[79]. The migration limits are based on RIVM (2008)[80] and correspond to 0.1% to 10% of the TDI (based on an assumed contribution of toys to the overall exposure of children).

According to the Toy Safety Directive concentration limits for CMR substances in toys apply as specified for classification of mixtures in the CLP Regulation (point 3, 4 and 5 of part III of Annex II of the Toys Directive, and point 3 and 4 of appendix B). The applicable limits in toys thus are:

- Carcinogenicity: ≥0.1% w/w for cat 1A and 1B, and ≥1% for cat 2 (Table 3.6.2 of the CLP Regulation)
- Mutagenicity: ≥0.1% w/w for cat 1A and 1B, and ≥1% for cat 2 (Table 3.5.2 of the CLP Regulation)
- Reproductive toxicity: ≥0.3% w/w for cat 1A and B, ≥3% for cat 2 (Table 3.7.2 of the CLP Regulation)

The generic concentration limits are rather high and are not substance specific (i.e. they do not consider potency) and thus are of limited value in getting a preliminary indication on possible concerns for a risk. The migration limits are more informative than the generic limits in indicating possible concerns for a risk as they are based on (a fraction of) substance-specific TDIs and a generic exposure assessment for children. For the purpose of the comparison it is assumed that the amount ingested, frequency and body weight are the same for infill as assumed in the derivation of the migration limits for toys. It is furthermore assumed, as a worst-case, that all of the substance will migrate out of the infill. On the other hand, considering the limited size of ingested particles it is not unlikely that most of the substance will under the harsh environment of the digestive system be mobilised from the matrix into the digestive juice.

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[78] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys
[79] http://ec.europa.eu/DocsRoom/documents/16183/attachments/1/translations and https://www.rivm.nl/bibliotheek/rapporten/320003001.pdf
[80] https://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

Based on comparison of the concentrations with limits in the Toy Safety Directive it would appear that there may be a risk from cobalt, chromium and zinc in rubber infill material that merits further assessment.

Table A 3.1 Concentration of substances in infill compared to limits of the substances in toys as established by the Toys Directive

Metal detected in studies	Concentration from studies (weighted average mg/kg=ppm)	Concentration from studies (range mg/kg=ppm)	Migration limit in Toys Directive for the metal *element* (mg/kg=ppm)	Concentration limit based on harmonised classification as CMR of the substance (mg/kg=ppm) *
1) Cobalt dichloride	32.1	3.5 - 268	**10.5**	≥1000 (≥0.1% w/w)
2) Chromium trioxide	5.3	0.3 - 56	Hexavalent chromium: **0.02** (trivalent chromium: 37.5)	≥1000 (≥0.1% w/w)
3) Nickel dichloride	2.9	0.6 – 26.12	75	≥1000 (≥0.1% w/w)
4) Zinc oxide/Ziram (zinc)	10 463.5	118 – 21000	**3 750**	-
5) Selenium	0.36	0 – 3.2	37.5	-
6) Beryllium	0.1	0.001 – 0.37	-	≥1000 (≥0.1% w/w)
7) Magnesium bis((R)-2-(2,4-dichlorophenoxy)propionate)	447.8	123 - 966	-	-
8) Divanadium pentaoxide	3.2	0.4 - 22	-	≥10 000 (≥1% w/w)
9) Lithium heptadecafluorooctanesulphonate	1.8	0.6 - 11	-	3000 (≥0.3% w/w)
10) N-1-naphthylaniline (PANA)	106.0		-	-

Metal detected in studies	**Concentration from studies (weighted average mg/kg=ppm)**	**Concentration from studies (range mg/kg=ppm)**	**Migration limit in Toys Directive for the metal *element*** **(mg/kg=ppm)**	**Concentration limit based on harmonised classification as CMR of the substance** **(mg/kg=ppm) ***
11) 1-methyl-2-pyrrolidone (N-methyl-2-pyrrolidone; NMP)	80	80-80	-	3000 (0.3 % w/w)
12) Mercury	0.14	0.03 - 3	7.5	3000 (≥0.3% w/w)

*The concentration given for each metal is based on the element. When the metal is part of a substance the atomic weight of the other elements in the substance play a role in the concentration and thus the concentration will be somewhat underestimated when compared to the limit for CMRs.