INVESTIGATION REPORT

Investigation of concentration limit for eight PAHs in loose rubber granules and mulches used in children's playground and other domestic applications to conclude whether the limit values set in Entry 50 of REACH Annex XVII are protective for very young children

SUBSTANCE NAME: Polycyclic aromatic hydrocarbons (PAHs)

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TABLE OF CONTENTS

About this report 1
Summary 2
1. Group of PAHs under investigation 5
2. Manufacture, import and use overview 6
2.1. Manufacture and use of rubber granules and mulches in loose form 6
2.2. Applicable concentration limits for PAHs' mixtures under REACH 8
2.3. PAH concentration in rubber granules and mulches 9
3. Exposure assessment 11
3.1. Main principles 11
3.2. Input parameters 12
3.3. Overview of input parameters 16
3.4. Exposure estimation 18
4. Risk characterisation 23
4.1. Children playing at playgrounds 23
4.2. Children playing in home gardens 25
4.3. Combined exposure (playgrounds + home gardens) 26
5. Assumptions and uncertainties 27
5.1. Hazard and risk 27
5.2. Use of rubber granules and mulches 27
6. Conclusions 29
ANNEX A – Exposure and Risk tables for all exposure scenarios considered in this work 31
ANNEX B - Lifelong exposure Scenario 36
ANNEX C - Summary of Internet research on granules and mulches in loose form used in domestic applications conducted by ECHA 39
References 47

TABLES

Table 1: Results of the exposure and risk assessment (all routes) 3

Table 2: REACH-8 PAHs 5

Table 3: Concentration limit values for individual REACH-8 PAHs set in Annex XVII entries 28-30 8

Table 4: Relative, normalised and calculated contribution of each REACH-8 PAHs in the typical rubber granule, deriving a maximum concentration limit of 387 mg/kg 9

Table 5: Anthropometric data 13

Table 6: General input parameters 16

Table 7: Dermal exposure (children playing at playground) 18

Table 8: Dermal exposure (domestic applications PAH content 20 mg/kg) 18

Table 9: Dermal exposure (domestic applications PAH content 53 mg/kg) 19

Table 10: Dermal exposure (domestic applications PAH content 387 mg/kg) 19

Table 11: Oral exposure (children playing at playgrounds) 20

Table 12: Oral exposure (domestic applications PAH content 20 mg/kg) 20

Table 13: Oral exposure (domestic applications PAH content 53 mg/kg) 20

Table 14: Oral exposure (domestic applications PAH content 387 mg/kg) 21

Table 15: Exposure by inhalation children playing at playgrounds 21

Table 16: Inhalation exposure (domestic applications PAH content 20 mg/kg) 22

Table 17: Inhalation exposure (domestic applications PAH content 53 mg/kg) 22

Table 18: Dermal exposure (domestic applications PAH content 387 mg/kg) 22

Table 19: Summary of unit risk levels 23

Table 20: Excess lifetime cancer risk for children playing at playground (all age ranges) – ('2019 parameters') 24

Table 21: Excess lifetime cancer risk for children playing at playground (all age ranges) – ('2023 parameters') 24

Table 22: Excess lifetime cancer risk for children playing in home gardens (PAH content 20 mg/kg) 25

Table 23: Excess lifetime cancer risk for children playing in home gardens (PAH content 53 mg/kg) 25

Table 24: Excess lifetime cancer risk for children playing in home gardens (PAH content 387 mg/kg) 26

Table 25: Combined excess lifetime cancer risk 26

Table 26: Exposure assessment and risk characterisation - input 'parameters 2023' 31

Table 27: Exposure assessment and risk characterisation – input 'parameters 2023' 32

Table 28: Exposure assessment and risk characterisation input 'parameters 2019' - content of PAHs: 20 mg/ kg 33

Table 29: Exposure assessment and risk characterisation input 'parameters 2019' - content of PAHs: 53 mg/ kg.....34

Table 30: Exposure assessment and risk characterisation input 'parameters 2019' - content of PAHs: 387 mg/ kg.....34

Table 31: Input parameters and exposure calculations (ECHA 2019a).....36

Table 32: Lifelong exposure and risk for children playing at playground (PAH content 20 mg/kg).....37

Table 33: Lifelong excess risk table for domestic application (total).....38

Table 34: Outcome of the internet searches.....42

LIST OF ACRONYMS AND ABBREVIATIONS

Acronym	Meaning
BaUA	German Federal Institute for Occupational Safety and Health
CLP	Regulation (EU) 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation)
ECHA	European Chemicals Agency
ELT	End of Life Tyres
ETRA	European Tyre Recycling Association
ETRMA	European Tyre and Rubber Manufacturers' Association
PAHs	Polycyclic Aromatic Hydrocarbons
REACH	Regulation (EU) 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation)
REACH-8 PAHs	PAHs in the scope of restriction entry 50 (eight substances)
RIVM	Dutch National Institute for Public Health and the Environment

About this report

On January 2023, the Commission requested ECHA to assess risks to children posed by Polycyclic Aromatic Hydrocarbons (PAHs) in granules and mulches used in loose form in playgrounds as well as other domestic applications such as gardening and landscaping.

The aim is to determine if the applicable content limits established by REACH for the sum of eight PAHs (REACH-8 PAHs) listed in entry 50 of Annex XVII to REACH are "*consistent with a high level of protection of human health*".

In accordance with the request from the Commission, ECHA:

1. Investigated the technical and scientific information included in the restriction report submitted by the Netherlands and ECHA in 2019 (ECHA, 2019d) and RAC and SEAC opinions related to that proposal with specific focus on exposure of children to PAHs.
2. Gathered available market data on possible use of rubber granules and mulches in loose form in domestic applications such as gardening and landscaping in the EU.
3. Reviewed the assumptions made and methodology used by the Netherlands and ECHA (ECHA, 2019d) in the exposure assessment for children included in the restriction report (in point 1) with the scope to perform an additional assessment to include very young children (1–2-year-old) and uses in domestic applications.
4. Determined the risk for children from exposure to PAHs obtained using reasonably worst-case assumptions (as per Commission's mandate) to conclude whether the risk is adequately controlled.
5. Provided conclusions on possible need to develop an Annex XV restriction proposal to address the identified risk.

The assumptions included in this report are based on information already available to ECHA at the time of preparation (e.g. information generated in the preparation and opinion development phase of the restriction proposal on PAHs in rubber granules and mulches used in sport applications and playgrounds (ECHA, 2019e)).

The scope of the work described in the dossier is limited to the assessment of the exposure to the REACH-8 PAHs for children and the characterisation of the risk.

Assessment of hazards, uses, alternatives and impacts are outside the scope of this work.

Summary

Rubber granules and mulches are regarded as **mixtures** in the scope of REACH.

Paragraphs 9 and 10 of REACH Annex XVII Entry 50 restrict the placing on the market and use of eight polycyclic aromatic hydrocarbons (REACH-8 PAHs) in granules and mulches used in loose form on playgrounds or in sport applications if they contain more than 20 mg/kg (0.002% weight by weight) of the sum of REACH-8 PAHs. The 20 mg/kg concentration limit is based on reasonably worst-case scenarios and has been recommended by RAC (ECHA, 2019e) in response to a lower limit (i.e. 17 mg/kg) proposed by the Netherlands in the restriction proposal to limit PAH content in rubber granules and mulches in loose form used in sport applications and playgrounds (ECHA, 2019d).

With regard to the presence of PAHs in granules and mulches used in domestic applications, the concentration limits for consumer mixtures set in REACH Annex XVII Entries 28 to 30 apply, which correspond to a concentration limit of 387 mg/kg for the sum of REACH-8 PAHs.

To enable the Commission to conclude whether the PAH content limits established in REACH for granules and mulches used in loose form in playgrounds and domestic applications (such as gardening and landscaping) are protective for children, ECHA developed specific exposure scenarios and assessed exposure and risks for children.

ECHA's assumptions, considerations and conclusions included in this report are based prevalently on:

- Information included in the Final Background Document (ECHA, 2019d) and Annex to the Background Document prepared by RAC and SEAC in relation to the restriction proposal on PAHs in rubber granules and mulches prepared by the Netherlands (ECHA 2019a);
- RAC and SEAC final opinion (ECHA, 2019e) on the restriction proposal on PAHs in rubber granules and mulches prepared by the Netherlands;
- Other information generated in the opinion development phase of the restriction on PAHs in rubber granules and mulches (2019) available in ECHA's registry of restriction intentions until outcome (ECHA, 2019b);
- Information from ECHA's internet research on availability on the market for consumer use of rubber granules and mulches from ELT in the EU;
- ECHA's investigation report on available analytical methods to measure content and migration of PAH limit values in rubber and plastic articles in paragraphs 5 and 6 of Entry 50 of REACH Annex XVII (ECHA 2020);
- Information provided by Industry and information gathered by ECHA on the internet on use of rubber granules and mulches in domestic applications in the EU.

The exposure assessments and risk characterisations included in this report cover children between 1 and 13 years old and have been developed using **reasonably worst-case assumptions.** Several input parameters used in the 2019 restriction proposal on PAHs in rubber granules and mulches ('2019 parameters') are reconsidered to reflect new insights (2023 parameters). The results are presented in the table below.

Table 1: Results of the exposure and risk assessment (all routes)

	Excess cancer risk ('2019 parameters')	**Excess cancer risk ('2023 parameters')**
Playgrounds (20 mg/kg PAH content)	1.42×10^{-6}	1.63×10^{-6}
Domestic applications (20 mg/kg PAH content)	1.17×10^{-6}	-
Domestic applications (53 mg/kg PAH content)	3.09×10^{-6}	-
Domestic applications (387 mg/kg PAH content)	-	2.26×10^{-5}
Combined risk (20 mg/kg PAH content for both playgrounds and domestic applications)	2.58×10^{-6}	-
Combined risk (20 mg/kg PAH content for playgrounds, and 53 mg/kg for domestic applications)	4.50×10^{-6}	-
Combined risk (20 mg/kg PAH content for playgrounds, and 387 mg/kg for domestic applications)	-	2.40×10^{-5}

In summary ECHA concludes that the limit of **20 mg/kg** for the sum of REACH-8 PAHs established for rubber granules and mulches in loose form can be considered **protective for children for use in playgrounds**. In line with RAC's opinion on the restriction proposal on rubber granules (ECHA, 2019d), ECHA considers also that such limit helps to significantly reduce children's exposure to PAHs by preventing the use of rubber granules and mulches with high PAH content in the EU.

In relation to PAH content in rubber granules and mulches **for use in domestic applications** (such as gardening and landscaping), ECHA concludes that a content limit of **20 mg/kg** and **53 mg/kg** (corresponding to the highest PAH content identified in the 2019 restriction proposal), for the sum of REACH-8 PAHs, can be considered **protective for children**.

ECHA concludes also that the **content limit for carcinogenic (1A and 1B) substances** in consumer mixtures set in restriction entry 28 for the sum of REACH-8 PAHs (i.e. which corresponds to **387 mg/kg**) is **not protective for children**. On one hand, there is evidence that loose rubber granules and mulches are available for on-line purchase, and therefore domestic uses cannot be excluded. On the other hand, no information is available on whether materials available for use in domestic settings differ, in terms of origin and PAH content, from granules and mulches used in playgrounds for which the content limit in restriction entry 50 applies (i.e. 20 mg/kg). Moreover, the use in the exposure assessment of a high PAH content (i.e. 387 mg/kg for the sum of REACH-8 PAHs) and reasonably worst-case assumptions may lead to an over-estimation of the risks. Additionally, it should be noted that rubber granules (whose dimensions range from 1 to 4 mm) for playground and domestic applications, will fall under the definition of microplastics, and will therefore be affected by this restriction once adopted. The draft legal act

for microplastics restriction has been recently approved by the REACH Committee (vote of 26 April 2023) [1].

In conclusion, ECHA **does not recommend to prepare an Annex XV restriction** report on PAHs in rubber granules and mulches in loose form in domestic applications and considers that a holistic approach to PAHs would be the most effective way to regulate these substances.

[1] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

1. Group of PAHs under investigation

Numerous PAHs have been investigated for their carcinogenic potential and many PAHs share the same genotoxic mechanism of action, i.e. metabolic activation to electrophilic dihydrodiol epoxides and/or quinones which are capable of covalent binding to DNA (WHO, 1998).

Consumers exposed to PAH-containing rubber granules and mulches will not be exposed to a single PAH but will inevitably be exposed to complex mixtures of probably up to several hundreds of PAHs (ECHA, 2019d).

The REACH-8 PAHs addressed by this report are presented in Table 2. They are already restricted under Annex XVII entry 50 and have a harmonised classification for carcinogenicity under the CLP regulation (Annex VI to Reg. (EC) No. 1272/2008). Furthermore, Benzo[a]Pyrene (BaP) and Chrysene (CHR) are classified for mutagenicity and (BaP) also for toxicity to reproduction and skin sensitisation under the CLP regulation (EU-Commission, 2020).

Table 2: REACH-8 PAHs

Substance	Acronym	CAS No	EC No
Benzo[a]pyrene	BaP	50-32-8	200-028-5
Benzo[e]pyrene	BeP	192-97-2	205-892-7
Benzo[a]anthracene	BaA	56-55-3	200-280-6
Chrysene	CHR	218-01-9	205-923-4
Benzo[b]fluoranthene	BbFA	205-99-2	205-911-9
Benzo[i]fluoranthene	BjFA	205-82-3	205-910-3
Benzo[k]fluoranthene	BkFA	207-08-9	205-916-6
Dibenzo[a,h]anthracene	DBAhA	53-70-3	200-181-8

Source: entry 50 of REACH Annex XVII

In addition to the REACH-8 PAHs addressed in this dossier, other PAHs possibly present in rubber granules and mulches may be genotoxic carcinogens. For example, two additional PAHs[2] have been classified as carcinogens 1B (Harmonised classification) in 2020.

Other PAH substances than the REACH-8 PAHs have not been included in the request from the Commission and are therefore not included in the scope of this work.

[2] benzo[rst]pentaphene: EC Number: 205-877-5, CAS Number: 189-55-9 (RAC opinion: Muta 2, Carc 1B) and dibenzo[b,def]chrysene, dibenzo[a,h]pyrene: EC Number: 205-878-0, CAS Number: 189-64-0 (RAC opinion: Muta 2, Carc 1B). RAC opinions: https://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling

2. Manufacture, import and use overview

2.1. Manufacture and use of rubber granules and mulches in loose form

The restriction proposal on PAHs in rubber granules and mulches in playgrounds and sport applications (ECHA, 2019d) provides extensive information on the manufacture of rubber granules and mulches from ELT in the EU and their use as infill material in synthetic turf pitches and in loose form on playgrounds and other sport applications.

2.1.1. Manufacture of loose granules and mulches

Rubber granules and mulches can be produced from a variation of virgin and recycled materials, however, majority of granules in the EU are produced from End-Of-Life Tyres (ELT). Other materials such as ethylene-propylene diene monomer (EPDM) are also used to produce rubber mulches, although, to a considerably less extent. Tyres generally contain PAHs from extender oil and carbon black used in tyre production or from degradation of other materials. PAH content in tyres has been decreasing since 1st of January 2010 due to the content limits imposed by restriction entry 50 of REACH Annex XVII in extender oils used in tyre manufacturing (ECHA, 2019c).

Rubber granules are defined as particles typically in the 1-4 mm-size range manufactured from rubber or other vulcanised or polymeric material of recycled or virgin origin or obtained from a natural source.

Rubber mulches are flake-shaped particles ranging in size from 4 mm up to 130 mm length (typically 10-40 mm) and 10-15 mm width, manufactured from rubber or other vulcanised or polymeric material of recycled or virgin origin or obtained from a natural source.

Based on information provided by industry and included in the restriction report (ECHA, 2019d) materials for rubber granules and mulches are mostly produced in the EU and imports of this material from outside the EU is assumed to be almost non-existent. Although recent data are not available to confirm whether this assumption is still valid nowadays, this assumption is still considered plausible.

2.1.2. Use in loose applications

Rubber granules and mulches are typically used in the following applications (ECHA, 2019c):

- Playgrounds
- Landscaping
- Gardens
- Parks
- Golf courses
- Nature trails
- Horse arena footing
- Athletic arenas
- Residential applications

The material may be used in loose form, but it is more often used in form of tiles obtained by bonding granules and mulches with a polyurethane based resin. (ETRA, 2023)[3]. Similar findings are reported in Annex C - Table 34. No data are available on the amount of rubber granules and mulches used in loose form compared to use in tiles.

Some use of mulches in loose form in playgrounds are observed in France, Germany, the UK, Austria, the Netherlands, Belgium, Bulgaria and Switzerland. Such uses are almost non-existent in Portugal, Spain, and Sweden (ECHA, 2019c). The use of rubber mulches is most prevalent in the UK when compared with EU Member States.

To gather more recent information on use of rubber granules and mulches in loose form for uses in domestic applications such as playgrounds, gardening and landscaping, ECHA performed a web-search in March 2023. The purpose was limited to gather updated information since 2019 on availability in the EU consumers' market. The research aimed only to obtain confirmation on whether an EU consumer market for these products exists. For this reason, the investigation focused on information publicly available on the internet in a limited number of EU countries (i.e. Belgium, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Spain, Sweden) and the UK. Also online non-EU retailers who were able to supply these products into the EU consumer market were looked at.

Local Google web browsers (in national languages) were used to conduct the research. The words "granules" or "mulches", translated into national languages, were used as search terms. Relevant suppliers have been contacted via email by ECHA with a request to provide information on amount of rubber mulches supplied in last years to consumers and possibly their PAH content (if known to the supplier). Please see details in Annex C.

The internet search confirmed the strong UK finding, and found many retailers from Germany, Belgium and Poland and no relevant hits in France, the Netherlands and Portugal.

The research returned also that online purchase by consumers of rubber granules and mulches in loose form from virgin materials and from recycled ELT is possible in the EU from a number of suppliers located in different EU member States and elsewhere. Twenty online retailers were found to supply rubber granules and mulches in the EU; twelve of them sell products directly to consumers while eight sell products mainly to industrial or professional customers.

The market of these products is global and tracking the origin of the material provided is very difficult. Alternative materials to rubber are available in the EU market. No market data or information on PAH content of granules and mulches supplied were provided by companies contacted by ECHA. A limited number of responses have been received highlighting that these products are purchased by companies rather than by consumers in most EU countries.

[3] Rubber tiles are articles under REACH. PAHs limit for articles "*that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use"* is set to 1mg/kg (Paragraph 5 of restriction Entry 50 of Annex XVII to REACH).

2.2. Applicable concentration limits for PAHs' mixtures under REACH

Rubber granules and mulches are regarded as **mixtures** in the scope of REACH as agreed upon by the European Commission (CARACAL paper CA/30/05/2016) and the content limits of PAHs in these mixtures are therefore regulated as follows:

- **20 mg/kg for the sum of REACH-8 PAHs** (see Table 2) in granules and mulches used as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications (Restriction entry 50 (paragraph 9 and 10))

- 100 or 1 000 mg/kg for each individual PAH (based on their classification) contained in granules and mulches supplied to the general public, and used in applications such as gardening or other domestic applications (see Table 3) which corresponds to a total of **387 mg/kg for the sum of REACH-8 PAHs** (see Table 4) (Restriction entries 28-30 applicable to consumer mixtures).

It should be noted that the PAH content limit for granules and mulches set in Restriction entry 50 (paragraph 9 and 10) has been introduced by Regulation (EU) 2021/1199 of 20/07/2021 amending Annex XVII of REACH as a result of a restriction proposal submitted by the Netherlands (ECHA, 2019d) which is based on **reasonably worst-case scenarios**.

Table 3: Concentration limit values for individual REACH-8 PAHs set in Annex XVII entries 28-30

Name	EC Number	CAS Number	CLP Annex VI	Limit value[4] (% w/w)	Limit value (mg/kg)
BaP	200-028-5	50-32-8; 63466-71-7	Carc. 1B Muta. 1B Repro. 1B	0.01	100
BeP	205-892-7	192-97-2	Carc. 1B	0.1	1 000
BaA	200-280-6	56-55-3; 1718-53-2	Carc. 1B	0.1	1 000
CHR	205-923-4	218-01-9; 1719-03-5	Carc. 1B Muta. 2	0.1	1 000
BbFA	205-911-9	205-99-2	Carc. 1B	0.1	1 000
BjFA	205-910-3	205-82-3	Carc. 1B	0.1	1 000
BkFA	205-916-6	207-08-9	Carc. 1B	0.1	1 000
DBAhA	200-181-8	53-70-3	Carc. 1B	0.01	100

[4] Limit value applicable based on harmonized classification as Carc. 1B (H350) (specific concentration limits applicable to Benzo[a]pyrene (BaP) and Dibenzo[a,h]anthracene (DBAhA))

With regard to the REACH restriction entries 28-30, it is important to note that the concentration limit for the sum of REACH-8 PAHs cannot be derived by summing up the concentration limits of the individual PAHs. The maximum concentration limit for the sum of the REACH-8 PAHs must be determined by applying an additivity approach (ECHA, 2019c).

The outcome is summarised in Table 4below.

Table 4: Relative, normalised and calculated contribution of each REACH-8 PAHs in the typical rubber granule, deriving a maximum concentration limit of 387 mg/kg[5]

Name	Typical weight fraction	Concentration limit (mg/kg)	Relative contribution (fraction)	Normalised contribution (fraction)	Calculated contribution (mg/kg)
BaP	0.14	100	0.14	0.545 (=1/0.26) x 0.14)	54.5
DbahA	0.035	100	0.035	0.136	13.6
BeP	0.3	1 000	0.03	0.117	117
BaA	0.12	1 000	0.012	0.047	46.7
BbF	0.15	1 000	0.015	0.058	58.4
BjF	0.039	1 000	0.0039	0.015	15.2
BkF	0.039	1 000	0.0039	0.015	15.2
CHR	0.17	1 000	0.017	0.066	66.2
Sum			0.2568	1 (normalised)	**387**

2.3. PAH concentration in rubber granules and mulches

The ingredients of rubber granules and mulches from ELT find their basis in tyre manufacturing. The oils that are conventionally used in tyre manufacturing are Highly Aromatic (HA) oils due to the fact that they are compatible with both natural and synthetic rubbers. Oils in tyres have the functionality of improving processing properties, low temperature properties, dispersion of fillers and to reduce costs. The use of these oils is one of the reasons why PAHs are present in tyres that can, after usage on a vehicle, be processed into ELT-derived rubber infill.

According to the RIVM risk assessment on rubber granules (RIVM, 2017), ELT made infill material used in artificial turf pitches have a median REACH-8 PAHs content of 5.8 mg/kg dry weight and a maximum of 19.8 mg/kg in the samples tested.

[5] See table B35b – Section B.10.2.1 of the Annex to the Background Document (ECHA 2019a)

ECHA found that new rubber granules manufactured from recycled tyres in the EU contain typically 0.2-22.8 mg/kg[6] of REACH-8 PAHs. Differences in PAH concentrations in rubber granules and mulches might occur for various reasons (ECHA, 2019c).

First of all variability may depend on the methods of extraction and analysis applied.

A second issue might be that other non-tyre derived waste material can be used to produce rubber granules and mulches with different PAH content than ELT.

A third issue is that very old scrap car or truck tyres or scrap non-automotive tyres (e.g. off-the-road tyres) may be used to manufacture granules (from before the entry into force of the EU extender oil restriction).

A fourth source of variation may be the use of imported tyres[7] that do not comply with the EU extender oil restriction to manufacture granules.

The results of a study from Depaolini et al. (2017) indicate a generally lower amount of PAHs in EU recycled rubber samples compared to the non-EU ones. Moreover, for the non-EU material there was a difference in PAH content in samples taken before and after 2010, while this difference was less evident for the EU samples. The only significant difference was between EU and non-EU tyres.

A recent paper of Armada Álvarez et al. (2022) compared PAHs and other hazardous components of ELT crumb rubber samples. Seventy-eight samples were collected from four continents and seventeen countries worldwide. The highest mean concentrations were measured in Finland (6.6 mg/kg) and Sweden (12 mg/kg). Almost all crumb rubber samples complied with the EU level of 20 mg/kg (only one sample from Sweden and two non-EU samples from Chile exceeded the value). The authors also noted that most crumb rubber samples exceeded the 1 mg/kg limit for the REACH-8 PAHs in consumer goods and materials *"with intensive contact with the human skin or oral cavity"* (paragraphs 5 and 6 of restriction entry 50 of REACH Annex XVII). The authors also concluded that it is difficult to relate the geographical origin of the sample to its chemical composition, as ELTs can be received from all parts of the world.

[6] The minimum and maximum values are calculated from different samples measured in one study. This is done in order to get the worst-case values. Studies from almost 10 Member States covering more than 100 pitches (infill material already in use) and around 50 samples of new recycled rubber granules.

[7] Note that imported tyres should also comply with the EU extender oil restriction and because of that are expected to be low in PAHs, similarly to tyres produced in the EU for the EU market. The difference in PAH content is especially expected in tyres that are produced for the non-EU market.

3. Exposure assessment

3.1. Main principles

The approach followed by ECHA for the exposure assessment reported in this document is based on the models used by the Netherlands and ECHA in the restriction proposal on PAHs in rubber granules and mulches in loose form in playgrounds and sport application (ECHA, 2019d). RAC considered that such approach *"is likely to overestimate exposure and excess lifetime risk"* (ECHA, 2019e).

ECHA also took in consideration a recent research study on "Existing default values and recommendations for exposure assessment" which has been published by The Nordic Exposure Group (NEXPO, 2023)[8] (TemaNord, 2023).

Children playing at playgrounds

The exposure assessment drawn up by the Netherlands in their restriction proposal (ECHA, 2019d), aimed at covering the 95th percentile of the exposed population, which is the typically used percentile for determining the **reasonably worst-case consumer exposure**. In the current assessment ECHA adopted additional conservative assumptions (2023 parameters):

1. inclusion of one additional contributing scenario for 1–2-year-old children
2. use of higher values for frequency and duration of the exposure as input parameters for the assessment of the exposure (See Table 6)
3. assumption that oral exposure by ingestion may occur also for very young children (1-2 years old) although it could be assumed that children at that age play at playgrounds under strict supervision by adults.

Children above 13-year-old and adults are not taken into account as they are out of the scope of this work. Although not specifically requested by the Commission, ECHA has also calculated lifetime exposure to PAHs and related risks (see Annex B).

The following exposure scenarios have been derived:

- Scenario 0: Child, 1 to 2-year-old playing on playground
- Scenario 1: Child, 2 to 3-year-old playing on playground
- Scenario 2: Child, 3- to 6-year-old playing on playground
- Scenario 3: Child, 6- to 11-year-old playing on playground
- Scenario 4: Child, 11 to 13-year-old playing on playground

Two different groups of input parameters, based on reasonably worst-case assumptions, have been considered for the estimation of exposure to PAHs and excess cancer risk.

In the first one (**'2019 parameters'**), the same parameters are used as in the restriction report on rubber granules (ECHA, 2019d).

[8] The Nordic Exposure Group (NEXPO) is an experts subgroup of the Nordic Council of Ministers, an intergovernmental organisation to promote cooperation and integration among Northern Countries. The group is constituted by government representatives of Denmark, Finland, Iceland, Norway, Sweden, the Faroe Islands, Geenland and Åland. https://www.norden.org/en

In the second one (**'2023 parameters'**), higher values for frequency and duration are used.

Domestic applications (gardening and landscaping)

Exposure and risks for use in domestic applications were not considered in the restriction report on PAHs in rubber granules (ECHA, 2019d). These uses are therefore not covered by paragraphs 9 and 10 of restriction Entry 50. The content limit of PAHs in rubber granules and mulches in domestic applications is set to 100 or 1 000 mg/kg (depending on the substance) by restriction entry 28 (for Carcinogenic properties) with a total of 387 mg/kg for the sum of the 8-REACH PAHs (see Table 4).

For this work it has been assumed that use of rubber granules and mulches in domestic applications takes place in the EU. Exposure scenarios have been prepared for children of same age groups than children playing in playgrounds considering the following different PAH contents:

Reasonably worst-case assumptions

- PAH content in rubber granules and mulches: 20 mg/kg (content limit in paragraphs 9 and 10 of restriction entry 50).
- PAH content in rubber granules and mulches: 53 mg/kg (maximum value reported during the ECHA consultation[9] on the restriction proposal on rubber granules (ECHA, 2019d) – see section 2.3. Although limited information is available, ECHA considered this content value to be informative for a PAH content between 20 and 387 mg/kg and decided to consider it in the risk calculation.
- PAH content in rubber granules and mulches: 387 mg/kg (content limit in restriction entry 28 for the sum of REACH-8 PAHs).

'2019 parameters' have been used in relation to body weight and body surface, amount of granules ingested, frequency of exposure, migration and PAH concentration in air. The duration time of each visit has been set to 50 minutes/day based on a study from the UK (2015). In line with (ECHA, 2019d) oral exposure for children 1-2 years old and children 11-13 has been considered unlikely.

3.2. Input parameters

The following sections contain a description of the parameters used in assessment of children's exposure to PAHs and risk characterisation with reference to relevant sources.

3.2.1. Body weight and body surface

For body weight and body surface area of different age children, the default values defined by RIVM (2014) are used. These values are based on the 25th percentile from Dutch population and are provided for all age groups (see Table 5).

[9] Comment #1939 in the response to comments document (RCOM) on the Annex XV dossier proposing a restriction on Polycyclic-aromatic hydrocarbons - https://echa.europa.eu/documents/10162/bed0e10a-e36e-df3c-5907-318886c1e215

Table 5: Anthropometric data

	Age	Average body weight, kg	Contact area of relevant parts, m^2		
			Hand	Leg	Feet
Scenario 0	1 to 2	9.8	0.014	0.051	0.015
Scenario 1	2 to 3	12.4	0.014	0.072	0.018
Scenario 2	3 to 6	15.7	0.017	0.088	0.022
Scenario 3	6 to 11	24.3	0.023	0.128	0.031
Scenario 4	11 to 13	44.8	0.032	0.211	0.048

Source: (RIVM, 2014)

3.2.2. Amount of rubber granules and mulches ingested by children

For the present assessment, ECHA assumed that children in all age groups (scenarios 0 to 4 above) may swallow a total of 90 mg/day of rubber granules or mulches. This value is coherent with US EPA estimate for the oral amount (90 mg/day) of soil that children from 1- to 12-year-old would swallow in one event (playground daily visit) (US-EPA, 2017) . The value is the upper (95^{th}) percentile value and it is also confirmed by the Nordic exposure group (NEXPO, 2023).

3.2.3. Amount of rubber granules on the skin (dermal load)

To calculate dermal exposure, it is first needed to determine the dermal load (i.e. amount of rubber granules in contact with skin) in line with the method used in the restriction proposal on PAH in rubber granules (ECHA, 2019d).

Dermal load is calculated, for each skin part (hands, legs and feet) using the frequency of contact of hands, legs and feet with rubber. The total dermal load is then obtained by summing up the loads calculated for individual parts (hands, legs and feet) separately. The following formula is used:

Dermal load for indivitual part (i.e. legs, hands, feet) = (surface area of the part) x (amount of rubber granules per cm^2) x (fraction remaining on skin) x (frequency of contact with skin part).

The following results have been obtained, and are reported in Table 6:

'2019 parameters' 261 days/year – hands and 66 days/year – feet and legs)

*Amount of granules on skin (g) for each scenario***:** 0.18, 0.21, 0.27, 0.56 and 0.87 g

'2023 parameters' (300 days/years - hands and 80 days/year – feet and legs

*Amount of granules on skin (g) for each scenario***:** 0.21, 0.25, 0.31, 0.65 and 1.00 g

3.2.4. Time spent by children in playground/domestic gardens

The restriction proposal by the Netherlands (ECHA, 2019d) considers that "**in the reasonably worst-case scenario** used for the exposure assessment (aiming at a 95^{th} percentile of the exposure, typically used percentile for consumer exposure), a child is assumed to visit a playground with rubber granules containing PAHs for a few hours per day, on a number of days per year, from the age of 2 up to and including 12".

US-EPA (2011) has estimated that children 1-11 years spend typically 36 to 132 minutes per day (mean values) outdoors (activity not specified) while the 95th percentile value for time spent playing on sand/gravel or grass is 121 minutes per day. The data from UK shows that school age children (primary school) spend around 2 hours per day outdoors (ECETOC, 2001)

In the restriction proposal on rubber granules (ECHA, 2019d) the Netherlands, used 2 hours to represent the duration of children's visit to playgrounds. This value is in line with the default values from US-EPA (2011), the UK (ECETOC, 2001) and the recommendation from the Nordic exposure group (NEXPO, 2023).

In this report, ECHA has conservatively considered a duration of visits to playgrounds of 3 hours/day.

3.2.5. Frequency of exposure

The frequency of skin contact used by the Netherlands in their restriction proposal (ECHA, 2019d) was set to 261 days per year. This parameter was adopted from RIVM (2016). The assumption is that children visit playgrounds 261 times in a year and have hand-contact with PAHs for the same number of days. The frequency of skin contact for legs and feet is assumed to be lower (66 days), since these body parts are considered to be covered by clothes and shoes for most of the time.

In the reasonably worst-case approach taken by ECHA in this report, the frequency of skin contact for hands, legs and feet has been set to 300 days/year. It is assumed that children visit playgrounds 10 months in a year (300 days) and have hand-contact with PAHs for the same number of days. The frequency of skin contact for legs and feet has been proportionally increased from the 66 days/year to 80 days/year.

3.2.6. PAHs concentration in air

Releases by evaporation of REACH-8 PAHs into air from rubber materials are unlikely because the REACH-8 PAHs substances are considered as low-volatile. Even in very hot summer days the evaporation of REACH-8 PAHs from uses of rubber granules and mulches is considered negligible based on measurements performed by Marsili (2015) and RIVM (2017). The approach taken in the restriction proposal on rubber granules (ECHA, 2019d) considered that inhalation exposure to PAH may be caused by airborne particles of rubber (rubber dust) produced by abrasion of rubber granules and mulches during playing. In this report ECHA used the air concentration of rubber dust (12 µg/m3), used also by the Netherlands in their restriction proposal (ECHA, 2019d). Such value was derived from measured data from indoor halls where rubber granules were used (NILU, 2006). This concentration value is suitable for a worst-case approach as it may be considered an overestimation when applied to children playing in playgrounds and domestic gardens, since the measurements by NILU were performed in indoor settings and during sport activities. The air concentration of rubber dust is used to calculate the concentration of BaP in air because the dose response relationship applied is derived for BaP which is used as an indicator for exposure.

The following formula is used: *BaP in air = PM10 rubber dust in air x REACH-8 PAHs content x Fraction BaP.*

3.2.7. Availability of PAH for exposure – migration from the rubber matrix

Exposure to PAH from rubber granules and mulches, may occur upon contact of substances released from rubber matrices with the skin or sweat, upon contact with gastro-intestinal fluids, and lung fluids. RIVM studies on oral and dermal migration (2017) have been considered in this work.

Based on RIVM approximately 9 % of the PAHs contained in the rubber granules/mulches are released into the gastrointestinal tract (RIVM, 2017). This value was adopted for the exposure estimation in the restriction proposal by the Netherlands (ECHA, 2019d) and it is also adopted the present report. In this report ECHA used, for dermal migration, a migration fraction of 0.05. This value has been taken from the restriction proposal on rubber granules (ECHA, 2019d) . The value has been derived from a study conducted by Fraunhofer (2017) using Tenax® as migration media for 10 days at 40°C. To be noted that, in this report and in line with the restriction proposal ECHA (2019d) the migration fractions from other studies were not considered. For example, the value of 0.02% derived by RIVM (2017) from a two-hour dermal migration study at 37°C using artificial sweat was considered an underestimation for dermal migration while the fraction of 0.086 for an individual PAH derived by JRC (2018) from a study conducted using 20% ethanol solution for 1, 4 and 24h at 40°C was considered not suitable for granules and mulches due to unrealistically high contact area of test material. In the absence of data on migration of PAH out of rubber dust into artificial lung fluid, as a worst-case assumption it was assumed that all PAH inhaled via rubber dust would become available for exposure.

3.2.8. Lifetime expectacy

Lifetime expectancy is a factor in the calculation of the excess cancer risk. A lifetime expectancy of 70 years has been used for this work in line with the restriction proposal on PAHs in rubber granules and mulches (ECHA, 2019d).

3.3. Overview of input parameters

Table 6 below includes a summary of all parameters, based on reasonably worst-case assumptions, used in the exposure assessment to PAHs for children playing in playgrounds and home gardens where rubber granules and mulches are used.

'2019 parameters' are marked in black and '2023 parameters' are marked in red.

Table 6: General input parameters

Parameter	Value	Unit	Reference
General			
Frequency (Nr) of visit (per year) to playgrounds (2019) and home gardens (2023)	261/365	day^{-1}	(RIVM, 2016)
Frequency of playground visit (2023)	300/365	day^{-1}	'2023 parameters'
Duration of playground visit 2019	2	h/day	(BAUA, 2010)
Duration of playground visit 2023	3	h/day	2023 parameters'
Time spent in domestic areas with rubber granules/mulches 2023	50	min/day	'2023 parameters'
Oral exposure			
Amount ingested (g) 2019 playgrounds	0.09 (2-10 year) 0 (11-13 year)		(US-EPA, 2017)
Amount ingested (g) 2023 playgrounds	0.09 (1-10 year) 0 (11-13 year)		'2023 parameters'
Amount ingested (g) 2023 domestic applications	0.09 (1-10 year) 0 (11-13 year)		'2023 parameters'
Frequency of ingestion playgrounds (2019) and domestic applications (2023)	261/365	day^{-1}	(ECHA, 2019d)
Frequency of ingestion (playgrounds) 2023	300/365	day^{-1}	'2023 parameters'
Dermal exposure			
Hands			
Frequency of playground visit with hand-ground contact 2019 and domestic applications 2023	261/365	day^{-1}	(RIVM, 2016)

Parameter	Value	Unit	Reference
Frequency of playground visit with hand-ground contact 2023	300/365	day^{-1}	'2023 parameters'
Legs			
Frequency of playground visit (2019) and domestic applications (2023) with leg-ground contact	66/365	day^{-1}	(RIVM, 2016)
Frequency of playground visit with leg-ground contact (2023)	80/365	day^{-1}	'2023 parameters'
Feet			
Frequency of playground visit (2019) and domestic applications (2023) with feet-ground contact	66/**365**	day^{-1}	(RIVM, 2016)
Frequency of playground visit (2023) with feet-ground contact	80/365	day^{-1}	'2023 parameters'
Amount granules (g) per cm^2	0.083		(RIVM, 2017)
Fraction sticking to skin	0.01; 0.015		Derived from RIVM (2017)
Amount granules on skin (calculated) 2019	0.18;0.21; 0.27;0.56;0.87	g	Calculated (see section 3.2.3)
Amount granules on skin (calculated) 2023	0.21;0.25; 0.31;0.65;1.00	g	Calculated (see section 3.2.3)
Inhalation exposure			
PM10 – rubber dust	12	$\mu g/m^3$	(RIVM, 2017) (NILU, 2006)
PAH content in rubber granules / mulches used in this report			
Playgrounds	20	mg/kg	Conc. limit in Restr. Entry 50 (par 9 and 10) for the sum of REACH-8 PAHs
Domestic applications	20	mg/kg	Conc. limit in Restr. Entry 50 (par 9 and 10) for the sum of REACH-8 PAHs
Domestic application	53	mg/kg	Max value provided during public consultation (PC Ref 1939) of restr. Proposal on rubber granules (ECHA, 2019d)
Domestic application	387	mg/kg	Concentration limit in Restr. Entry 28 for the sum of REACH-8 PAHs

3.4. Exposure estimation

Exposure by dermal contact, oral ingestion and inhalation have been considered in this report for children playing at playgrounds and playing in domestic gardens where rubber granules and mulches are used.

Calculations have been performed considering a PAHs' content of 20 mg/mg, with '2019 parameters' and '2023 parameters' for playgrounds and a PAHs' content of 20, 53 and 387 mg/kg with '2019 parameters' for domestic applications.

3.4.1. Dermal exposure

Dermal exposure is obtained from dermal load, the concentration of REACH-8 PAHs in the granules, the migration fraction and body weight. In this report ECHA assumed a concentration of PAHs in granules of 20 mg/kg as established in restriction entry 50 (for playgrounds) and for PAH contents of 20, 50 and 387 mg/kg for domestic applications. The following formula is used:

Dermal exposure (µg/kg bw/day) = Amount of granules on skin x REACH-8 PAHs content x dermal migration fraction/ body weight x number of years in the age category /70 years.

Table 7: Dermal exposure (children playing at playground)

Scenario (playground)	Dermal exposure (µg/kg bw/day) '2019 parameters'	Dermal exposure (µg/kg bw/day) '2023 parameters'
Scenario 0 – child playground 1-2 yo	2.66×10^{-6}	3.14×10^{-6}
Scenario 1 – child playground 2-3 yo	2.51×10^{-6}	2.99×10^{-6}
Scenario 2 – child playground 3-6 yo	7.26×10^{-6}	8.63×10^{-6}
Scenario 3 – child playground 6-11 yo	1.65×10^{-5}	1.97×10^{-5}
Scenario 4 – child playground 11-13 yo	5.54×10^{-6}	6.60×10^{-6}

Table 8, Table 9, and Table 10 below report dermal exposure estimation for children playing at home calculated by ECHA for different PAH content in rubber granules.

Table 8: Dermal exposure (domestic applications PAH content 20 mg/kg)

Scenario – Domestic 20 mg/kg	Dermal exposure (µg/kg bw/day)
Scenario 0 – child domestic 1-2 yo	3×10^{-6}
Scenario 1 – child domestic 2-3 yo	3×10^{-6}
Scenario 2 – child domestic 3-6 yo	7×10^{-6}
Scenario 3 – child domestic 6-11 yo	1.7×10^{-5}
Scenario 4 – child domestic 11-13 yo	6×10^{-6}

Table 9: Dermal exposure (domestic applications PAH content 53 mg/kg)

Scenario – Domestic 53 mg/kg	Dermal exposure (µg/kg bw/day)
Scenario 0 – child domestic 1-2 yo	7×10^{-6}
Scenario 1 – child domestic 2-3 yo	7×10^{-6}
Scenario 2 – child domestic 3-6 yo	1.9×10^{-5}
Scenario 3 – child domestic 6-11 yo	4.4×10^{-5}
Scenario 4 – child domestic 11-13 yo	1.5×10^{-6}

Table 10: Dermal exposure (domestic applications PAH content 387 mg/kg)

Scenario – Domestic 387 mg/kg	Dermal exposure (µg/kg bw/day)
Scenario 0 – child domestic 1-2 yo	5.1×10^{-5}
Scenario 1 – child domestic 2-3 yo	4.9×10^{-5}
Scenario 2 – child domestic 3-6 yo	1.4×10^{-4}
Scenario 3 – child domestic 6-11 yo	3.2×10^{-4}
Scenario 4 – child domestic 11-13 yo	1.07×10^{-4}

3.4.2. Oral exposure

Oral exposure may occur by hand-to mouth contact and by ingestion. Due to limited information and uncertainties on the assessment of hand to mouth contact, ECHA has followed the approach taken by the Netherlands in the restriction proposal on rubber granules (ECHA, 2019d) and assumed that a fixed amount is ingested by children each time they visit a playground. Information on the amount ingested is established from US EPA (2011 and 2017) to 90 mg/event for children (1 - 11 year-old) and 50 mg/event (11 year-old and up). In the present assessment, ECHA assumed that oral ingestion may occur also for 1 - 2 year-old children playing at playgrounds. In the restriction proposal on rubber granules (ECHA, 2019d) this age range was not considered, assuming that children visit playgrounds starting from the age of 2. Ingestion for 1 - 2 year-old children playing at home gardens and for 11 - 13 year-old children (in all settings) is considered unlikely. Oral exposure is calculated by taking into account the amount of granules ingested by children and their PAH content, frequency (annual and weekly), oral migration fraction and body weight.

Oral exposure *(µg/kg bw/day) = Amount granules ingested x REACH-8 PAHs content x frequency/year x frequency/week[10] x oral migration fraction/ body weight x years in the age category/70 years.*

Table 11: Oral exposure (children playing at playgrounds)

Scenario	**Oral exposure (µg/kg bw/day) '2019 parameters'**	**Oral exposure (µg/kg bw/day) '2023 parameters'**
Scenario 0 – child playground 1-2 yo (new!)	0.000169	0.000194
Scenario 1 – child playground 2-3 yo	0.000133	0.000153
Scenario 2 – child playground 3-6 yo	0.000316	0.000363
Scenario 3 – child playground 6-11 yo	0.000341	0.000391
Scenario 4 – child playground 11-13 yo	0.00000	0.000000

Table 12: Oral exposure (domestic applications PAH content 20 mg/kg)

Scenario – Domestic 20 mg/kg	**Oral exposure (µg/kg bw/day)**
Scenario 0 – child domestic 1-2 yo	0.000000
Scenario 1 – child domestic 2-3 yo	0.000133
Scenario 2 – child domestic 3-6 yo	0.000316
Scenario 3 – child domestic 6-11 yo	0.000341
Scenario 4 – child domestic 11-13 yo	0.000000

Table 13: Oral exposure (domestic applications PAH content 53 mg/kg)

Scenario – Domestic 20 mg/kg	**Oral exposure (µg/kg bw/day)**
Scenario 0 – child domestic 1-2 yo	0.000000
Scenario 1 – child domestic 2-3 yo	0.000354
Scenario 2 – child domestic 3-6 yo	0.000838
Scenario 3 – child domestic 6-11 yo	0.000902
Scenario 4 – child domestic 11-13 yo	0.000000

[10] Frequency per week =1 since frequency per year is expressed in days.

Table 14: Oral exposure (domestic applications PAH content 387 mg/kg)

Scenario – Domestic 20 mg/kg	Oral exposure (µg/kg bw/day)
Scenario 0 – child domestic 1-2 yo	0.000000
Scenario 1 – child domestic 2-3 yo	0.002582
Scenario 2 – child domestic 3-6 yo	0.006119
Scenario 3 – child domestic 6-11 yo	0.006589
Scenario 4 – child domestic 11-13 yo	0.000000

3.4.3. Inhalation exposure

Exposure via inhalation is assumed to occur by inhalation of rubber dust (airborne particles) by children during their time spent in playgrounds or in domestic gardens where rubber granules and mulches are present. Inhalation exposure is calculated by considering the air concentration of rubber dust of 12 µg/m^3 (see section 1.4.1.5 of this report), PAH content fraction in rubber granules and mulches, BaP fraction and taking into account the duration and frequency of exposure (time spent by children per year and per week in playgrounds and home gardens where rubber granules are used).

The Formula is:

Inhalation exposure: *PM10 rubber dust in air x REACH-8 PAHs content x Fraction BaP x hours/d x frequency/year x frequency/week[11] x years in the age category/70 years.*

Table 15: Exposure by inhalation children playing at playgrounds

Scenario	Inhalation exposure (BaP µg/m^3) '2019 parameters'	Inhalation exposure (BaP µg/m^3) '2023 parameters'
Scenario 0 – child playground 1-2 yo	2.15 x 10^{-6}	3.70 x 10^{-6}
Scenario 1 – child playground 2-3 yo	2.15 x 10^{-6}	3.70 x 10^{-6}
Scenario 2 – child playground 3-6 yo	6.44 x 10^{-6}	1.11 x 10^{-5}
Scenario 3 – child playground 6-11 yo	1.07 x 10^{-5}	1.85 x 10^{-5}
Scenario 4 – child playground 11-13 yo	4.92 x 10^{-6}	7.40 x 10^{-6}

[11] Frequency per week =1 since frequency per year is expressed in days.

Table 16: Inhalation exposure (domestic applications PAH content 20 mg/kg)

Scenario – Domestic 20 mg/kg	**Inhalation exposure (BaP µg/m³)**
Scenario 0 – child domestic 1-2 yo	9×10^{-7}
Scenario 1 – child domestic 2-3 yo	9×10^{-7}
Scenario 2 – child domestic 3-6 yo	2.7×10^{-6}
Scenario 3 – child domestic 6-11 yo	4.5×10^{-6}
Scenario 4 – child domestic 11-13 yo	1.8×10^{-6}

Table 17: Inhalation exposure (domestic applications PAH content 53 mg/kg)

Scenario – Domestic 53 mg/kg	**Inhalation exposure (BaP µg/m³)**
Scenario 0 – child domestic 1-2 yo	2.4×10^{-6}
Scenario 1 – child domestic 2-3 yo	2.4×10^{-6}
Scenario 2 – child domestic 3-6 yo	7.1×10^{-6}
Scenario 3 – child domestic 6-11 yo	1.18×10^{-5}
Scenario 4 – child domestic 11-13 yo	4.7×10^{-6}

Table 18: Dermal exposure (domestic applications PAH content 387 mg/kg)

Scenario – Domestic 387 mg/kg	**Inhalation exposure (BaP µg/m³)**
Scenario 0 – child domestic 1-2 yo	1.73×10^{-5}
Scenario 1 – child domestic 2-3 yo	1.73×10^{-5}
Scenario 2 - child domestic 3-6 yo	5.19×10^{-5}
Scenario 3 – child domestic 6-11 yo	8.65×10^{-5}
Scenario 4 – child domestic 11-13 yo	3.46×10^{-5}

4. Risk characterisation

The REACH 8 PAHs investigated in this report are genotoxic carcinogens. Given the ability to induce genotoxic effects there is no threshold value below which no health risk exist for these PAHs. As indicated in ECHA's guidance on "characterisation of dose [concentration]-response for human health" (Chapter R8) in case of non-threshold substances a reference risk level which is considered to be of very low concern (DMEL) should be derived. Cancer risk level of 10^{-6} is seen as an indicative tolerable risk level when setting DMELs for the general population.

The assessment of hazard properties of the REACH-8 PAHs is outside the scope of this work. Hazard information and related risk levels for carcinogenic properties for REACH-8 PAHs are taken form the Restriction proposal on rubber granules (ECHA, 2019d) and reported in Table 19.

Excess lifetime cancer risk estimates for children playing at playgrounds and in home gardens aged 1 to 13 years for oral, dermal and inhalation routes are reported in the following sections.

Risk estimates for specific age ranges are reported in Annex A to this document. Excess cancer risks have been calculated for the exposure scenarios obtained by applying reasonably worst-case assumptions using '2019 parameters' and '2023 parameters'.

Total risk estimates have been conservatively calculated by summing up risks from different exposure routes. This conservative approach is in line with the approach taken by the Netherlands in the restriction proposal on PAHs in rubber granules (ECHA, 2019d) to overcome the "uncertainties that may result from differences in modes of action of tumour formation per route".

Excess cancer risk for oral, dermal and inhalation routes are calculated by multiplying exposure values (see section 3 above) by unit risk levels (see Table 19).

Table 19: Summary of unit risk levels

BMDL oral (µg/kg bw/d)	**BMDL dermal** (µg/kgbw/d)	**inhalation**
490	740	Dose-response relationship
Unit cancer risk per µg/kg bw/d	*Unit cancer risk per µg/kg bw/d*	*Unit cancer risk µg BaP/m3 - years*
0.001428571	**0.000945946**	**0.0004242**
These values are used to calculate oral and dermal excess risks. The values are taken from the Background document (ECHA 2019b) and validated by RAC. RAC has identified some uncertainties in the hazard assessment that are inherent to complex mixtures of substances. However RAC concluded that *"The approach used for this restriction is pragmatic and conservative with respect to the composition of the mixture". (see page 46 of Final RAC opinion, ECHA (2019a))*		

4.1. Children playing at playgrounds

Table 20 and Table 21 below reports the excess cancer risk for children 1-13 year-old (all age ranges) playing at playgrounds for dermal, oral and inhalation routes obtained by applying '2019 parameters' and '2023 parameters'. Excess cancer risk estimates are reported in Annex A to this

document for each specific age range and for content of PAHs in rubber granules and mulches of 20 mg/kg.

Table 20: Excess lifetime cancer risk for children playing at playground (all age ranges) – ('2019 parameters')

Route	**Excess cancer risk (all age ranges)**
Oral	1.37×10^{-6}
Dermal	3.26×10^{-8}
Inhalation	1.09×10^{-8}
Total	**1.42×10^{-6}**

Table 21: Excess lifetime cancer risk for children playing at playground (all age ranges) – ('2023 parameters')

Route	**Excess cancer risk (all age ranges)**
Oral	1.57×10^{-6}
Dermal	3.88×10^{-8}
Inhalation	1.88×10^{-8}
Total	**1.63×10^{-6}**

4.2. Children playing in home gardens

Excess cancer risk have been calculated for domestic applications for different PAH content in rubber granules of 20, 53 and 387 mg/kg taking into account the exposure estimations reported in sections 3.4.1, 3.4.2, and 3.4.3 for dermal, oral and inhalation routes.

Table 22: Excess lifetime cancer risk for children playing in home gardens (PAH content 20 mg/kg)

Route	**Excess cancer risk (all age ranges)**
Oral	1.13×10^{-6}
Dermal	3.26×10^{-8}
Inhalation	4.55×10^{-9}
Total	**1.17×10^{-6}**

Table 23: Excess lifetime cancer risk for children playing in home gardens (PAH content 53 mg/kg)

Route	**Excess cancer risk (all age ranges)**
Oral	2.99×10^{-6}
Dermal	8.65×10^{-8}
Inhalation	1.21×10^{-8}
Total	**3.09×10^{-6}**

Table 24: Excess lifetime cancer risk for children playing in home gardens (PAH content 387 mg/kg)

Route	Excess cancer risk (all age ranges)
Oral	2.18×10^{-5}
Dermal	6.32×10^{-7}
Inhalation	8.80×10^{-8}
Total	**2.26×10^{-5}**

4.3. Combined exposure (playgrounds + home gardens)

ECHA calculated also a combined excess cancer risk under the assumption that children play on the playgrounds in day-care or school during the day (for 2 hours/day) and play also in home gardens in the same days after day care or school. In this situation, children are considered to be in contact with rubber granules for 2 hours in playground and for additional 50 minutes at home for 261 days in a year.

Table 25: Combined excess lifetime cancer risk

Scenario	Excess risk oral	Excess risk dermal	Excess risk inhalation	Excess risk All routes
Playgrounds: PAH 20 mg/kg + Domestic: PAH 20 mg/kg	2.50×10^{-6}	6.52×10^{-8}	5.64×10^{-9}	**2.58×10^{-6}**
Playgrounds: PAH 20 mg/kg + Domestic: PAH 53 mg/kg	4.36×10^{-6}	1.19×10^{-7}	2.30×10^{-8}	**4.50×10^{-6}**
Playgrounds: PAH 20 mg/kg + Domestic: PAH 387 mg/kg	2.32×10^{-5}	6.71×10^{-7}	9.89×10^{-8}	**2.40×10^{-5}**

5. Assumptions and uncertainties

5.1. Hazard and risk

Uncertainties on the hazard side are due to the variability of the compositions of the PAH mixtures used in different toxicological and epidemiological studies used as reference for the risk assessment and the fact that these compositions may differ from the PAH composition of rubber granules and mulches from ELT.

Another uncertainty is related to the fact that both the restriction proposal and the present work limited the investigation to the REACH-8 PAHs included in entry 50 of REACH Annex XVII. It is clarified in the restriction report (ECHA, 2019d) and in the opinion by RAC (ECHA, 2019a) that REACH-8 PAHs are used as an indicator of other PAHs and that limiting their concentrations in mixtures and articles reduce the presence of other PAHs of potentially similar hazard profile.

Other PAHs not included in the group of REACH-8 PAHs may be genotoxic carcinogenic as well and could point towards an underestimation of risks. In this work ECHA applied a conservative approach (ECHA, 2019d) by summing up risk levels from different exposure routes to overcome the uncertainties that may result from different mode of action of cancer development per route.

5.2. Use of rubber granules and mulches

ECHA notes the following uncertainties regarding the use of loose rubber granules and mulches in the EU:

1- Origin and related PAH content in the rubber granules and mulches placed on the market in Europe

As explained in section 2.3, PAH content in rubber granules and mulches derives from ELT used in their production and this amount may vary based on the origin of ELTs. ECHA assumes that the loose granules and mulches that can be used in domestic applications come from the same sources than the materials used in playgrounds for which the PAH content limit in restriction 50 applies (20 mg/kg). Therefore, the PAH content-range is likely to be similar in both applications. However, as the PAH REACH restriction limit for domestic use is much higher than 20 mg/kg (see Table 4), ECHA considered potential values of 20, 53 mg/kg and 387 mg/kg for domestic use.

As described in section 2.3, the latest value (i.e. 387 mg/kg) corresponds to the content limit established in restriction Entry 28 of Annex XVII to REACH for the sum of REACH-8 PAHs in mixtures. This value is a theoretical maximum value which is not corroborated by data available on PAH content in rubber granules and mulches used in the EU.

The assumption of higher PAH content in loose granules and mulches used in domestic applications (compared to use in playgrounds) and associated uncertainty lead to an over-estimation of the exposure and the risk.

2- Existence of an EU consumer market (see section 2.1)

There is evidence that loose rubber granules and mulches are available for on-line purchase for domestic uses, so such uses cannot be excluded.

Based on information provided by EU industry (ETRA, 2023, ETRMA, 2023), granules and mulches are in most cases bound together in tiles using polyurethane resins and rarely used in loose form. Rubber tiles are articles under REACH, therefore individual PAH content limit of 1 mg/kg set in Entry 50 of Annex XVII to REACH (paragraph 5) is applicable.

Furthermore, industry reported that use of granules and mulches in loose form in domestic applications is limited to some uses in the UK and almost non-existent in the European Union.

The outcome of the web-search made by ECHA on availability on consumer market of these materials in loose form demonstrates that such use is possible although information is limited (use in playgrounds) or very scarce (use in domestic applications, such as gardening and landscaping).

As a worst-case scenario, in the assessment of risk for children, ECHA has assumed that rubber granules and mulches in loose form are commonly used in domestic applications. However, the uncertainty regarding the scale of use is likely to lead to an over-estimation of the exposure, and the risk.

6. Conclusions

Risk for children playing at playgrounds

Excess cancer risk for children during their childhood increases from 1.41 x 10^{-6} ('2019 parameters') to 1.63 x 10^{-6} ('2023 parameters').

ECHA has also calculated the lifelong risk (not included in the request from the Commission) under worst-case conditions: considering that after childhood a person may be exposed to PAHs also in adult age by playing sports in fields where rubber granules are used as infill material in line with the assumptions made in the restriction proposal on rubber granules and mulches (ECHA, 2019d).

Lifelong cancer excess risks calculated is 3.1 x 10^{-6} for use of rubber granules and mulches in playgrounds and sport fields (PAH content: 20 mg/kg). For use of rubber granules and mulches in domestic settings and sport fields, lifelong cancer risk varies between 2.52 x 10^{-6} (for PAH content of 20 mg/kg) to 2.4 x 10^{-5} (for PAH content of 387 mg/kg) (see Annex B)

Risk for children in domestic applications

In relation to use of rubber granules and mulches for domestic applications, risk levels for children derived by ECHA are in the range of 1.17 x 10^{-6} for PAH content of 20 mg/kg, 3.09 x 10^{-6} for PAH content of 53 mg/kg and 2.26 x 10^{-5} for a PAH content of 387 mg/kg.

Combined risk

ECHA has also calculated the combined excess cancer risk for children under the conservative assumption that children play at playgrounds in day-care or school during day and spend some time outdoors at home gardens covered by loose rubber granules or mulches after school.

Combined risk levels would be 2.58 x 10^{-6} for PAH content of 20 mg/kg in both playground and domestic applications, 4.50 x 10^{-6} for PAH concentration of 20 mg/kg in playgrounds and 53 mg/kg in domestic applications and 2.40 x 10^{-5} for PAH content of 20 mg/kg in playgrounds and 387 mg/kg in domestic applications.

Overall conclusion

For playgrounds, the application of '2023 parameters' and the inclusion of one additional scenario to cover children from 1-2 years old did not bring a significant increase in exposure and risk levels if compared to the conditions applied in the restriction proposal from the Netherlands (ECHA, 2019d). Excess cancer risk for children remains in the same range as in the restriction proposal even when '2023 parameters' are used.

For domestic applications, the results from exposure assessment and risk characterisation obtained by ECHA show that, under reasonably worst-case conditions, the excess cancer risk varies between 1.63 x 10^{-6} and 4.5 x 10^{-6} when the PAH content is kept between 20 mg and 53 mg/kg. Risk level is in the range of 10^{-5} when high PAH contents are assumed in granules and mulches used in domestic applications (i.e. 387 mg/kg).

In summary ECHA concludes that, in line with RAC's opinion on the restriction proposal on rubber granules (ECHA, 2019e), an excess cancer risk slightly above 10^{-6}, is obtained under worst-case assumptions, therefore **the content limit of 20 mg/kg** (for the sum of REACH-8 PAHs) established for rubber granules and mulches in loose form **can be considered protective** for children for **uses in playgrounds and domestic applications**. Moreover, such content limit helps to significantly reduce children's exposure to PAHs by preventing the use of rubber granules and mulches with high PAH content in the EU.

In relation to **use of rubber granules and mulches in domestic applications** (such as gardening and landscaping), ECHA considers that **the content limit for carcinogenic (1A and 1B) substances in consumer mixtures** set in restriction entry 28 for the sum of REACH-8 PAHs (i.e. corresponding to 387 mg/kg) **is not protective for children**. However, based on the information available at the time of preparation of this report and the associated uncertainties, it cannot be concluded whether such use poses a risk for EU children. Information on use and PAHs content of rubber granules and mulches in loose form in domestic applications in the EU is indeed very scarce. There is evidence that loose rubber granules and mulches are available for on-line purchase. Therefore, domestic uses cannot be excluded, although such use is not expected to be widespread. However, there is no indication that materials for use in domestic settings differ, in terms of origin and PAH content, from granules and mulches used in playgrounds for which the content limit in restriction entry 50 apply (i.e. 20 mg/kg).

Finally, ECHA highlights that rubber granules (whose dimensions range from 1 to 4 mm) comply with the definition of microplastics and may be therefore covered by the restriction on microplastics which has been adopted by the REACH Committee: placing on the EU market of rubber granules will be banned within 8 years from the entry into force of the restriction for uses in synthetic sport surfaces. In addition, the placing on the market of loose rubber granules for all other uses (playground and domestic) will be banned at the time of entry into force.

In light of the above considerations, ECHA encourages the Member States of the EU to closely monitor import, production and use of loose rubber granules and mulches for domestic applications in the EU to ensure that products on consumer market that can be used in domestic applications have a PAH content in the range of granules and mulches used in playgrounds.

In consideration of the reasonably worst-case assumptions adopted in the assessment of risks described above, the uncertainties identified and the number of regulatory actions currently in place to limit exposure to PAHs, **ECHA does not recommend to prepare an Annex XV restriction report on PAHs in rubber granules and mulches in loose form in domestic applications**.

ECHA concludes that a holistic risk management approach should effectively contribute to address risks from exposure to PAHs and allow for an efficient use of resources. Such approach should include the enlargement of the list of restricted PAHs, the review of the exposure and of the content limits for mixtures and articles containing PAHs in light of available new information on migration and availability of more advanced analytical methods, the inclusion of additional uses under the scope of restriction entry 50 to take into account applications not currently covered and for which risks have not been assessed.

ANNEX A – Exposure and Risk tables for all exposure scenarios considered in this work

Exposure assessment and risk characterisation – children playing at playgrounds

Table 26: Exposure assessment and risk characterisation - input 'parameters 2023'

	exp oral (µg/kg bw/day)	exp dermal (µg/kg bw/day)	exp inh (BaP µg/m³)	Excess risk oral	Excess risk dermal	Excess risk inhalation	Excess risk all routes
Scenario 0 - child playground 1-2 yo	0.000169	2.66E-06	2.15E-06	2.41E-07	2.51E-09	9.10E-10	
Scenario 1 - child playground 2-3 yo	0.000133	2.51E-06	2.15E-06	1.91E-07	2.38E-09	9.10E-10	
Scenario 2 - child playground 3-6 yo	0.000316	7.26E-06	6.44E-06	4.52E-07	6.87E-09	2.73E-09	
Scenario 3 - child playground 6-11 yo	0.000341	1.65E-05	1.07E-05	4.89E-07	1.56E-08	4.55E-09	
Scenario 4 - child playground 11-13 yo	0.00000	5.54E-06	4.92E-06	0	5.24E-09	1.82E-09	
Excess risk				**1.37E-06**	**3.26E-08**	**1.09E-08**	**1.41E-06**

Table 27: Exposure assessment and risk characterisation – input 'parameters 2023'

	exp oral (µg/kg bw/day)	**exp dermal (µg/kg bw/day)**	**exp inh (BaP µg/m3)**	**Excess risk oral**	**Excess risk dermal**	**Excess risk inhalation**	**Excess risk all routes**
Scenario 0 - child playground 1-2 yo (new!)	0.000194	3.14E-06	3.70E-06	2.77E-07	2.97E-09	1.57E-09	
Scenario 1 - child playground 2-3 yo	0.000153	2.99E-06	3.70E-06	2.19E-07	2.83E-09	1.57E-09	
Scenario 2 - child playground 3-6 yo	0.000363	8.63E-06	1.11E-05	5.19E-07	8.16E-09	4.71E-09	
Scenario 3 - child playground 6-11 yo	0.000391	1.97E-05	1.85E-05	5.59E-07	1.86E-08	7.84E-09	
Scenario 4 - child playground 11-13 yo	0.000000	6.60E-06	7.40E-06	0	6.24E-09	3.14E-09	
Sum excess risk				**1.57E-06**	**3.88E-08**	**1.88E-08**	**1.63E-06**

Exposure assessment and risk characterisation – domestic applications[12]

Table 28: Exposure assessment and risk characterisation input 'parameters 2019' - content of PAHs: 20 mg/ kg

	exp oral (µg/kg bw/day)	exp dermal (µg/kg bw/day)	exp inh (BaP µg/m3)	Excess risk oral	Excess risk dermal	Excess risk inhalation	Excess risk all routes
Scenario 0 - child 1-2 yo (new!)	0.000000	0.000003	0.0000009	0.00E+00	2.51E-09	3.79E-10	
Scenario 1 - child 2-3 yo	0.000133	0.000003	0.0000009	1.91E-07	2.38E-09	3.79E-10	
Scenario 2 - child 3-6 yo	0.000316	0.000007	0.0000027	4.52E-07	6.87E-09	1.14E-09	
Scenario 3 - child 6-11 yo	0.000341	0.000017	0.0000045	4.86E-07	1.56E-08	1.90E-09	
Scenario 4 – child 11-13 yo	0.000000	0.000006	0.0000018	0.00E+00	5.24E-09	7.58E-10	
Sum excess risk				**1.13E-06**	**3.26E-08**	**4.55E-09**	**1.17E-06**

[12] It is assumed that children exposure to PAHs is determined by the use of rubber granules in home gardens. It is assumed that children aged 1-2 years old would be closely supervised, therefore oral contact by ingestion is considered unlikely. Similarly unlikely is assumed oral contact (by ingestion) for children aged 11-13.

To calculate the time spent in home gardens by children a study by UK National Office for Statistics has been taken into account (Data from 2014 and 2015). The study considers that children 8-15 y/old in the UK spend an average of 50 minutes in activities. For this report it is conservatively assumed that the same time is spent for all age ranges (1-13 years old) in home gardens covered by rubber granules.

Table 29: Exposure assessment and risk characterisation input 'parameters 2019' - content of PAHs: 53 mg/ kg

	exp oral (µg/kg bw/day)	exp dermal (µg/kg bw/day)	exp inh (BaP µg/m3)	Excess risk oral	Excess risk dermal	Excess risk inhalation	Excess risk all routes
Scenario 0 - child 1-2 yo (new!)	0.000000	0.000007	0.0000024	0.00E+00	6.66E-09	1.00E-09	
Scenario 1 - child 2-3 yo	0.000354	0.000007	0.0000024	5.05E-07	6.30E-09	1.00E-09	
Scenario 2 - child 3-6 yo	0.000838	0.000019	0.0000071	1.20E-06	1.82E-08	3.01E-09	
Scenario 3 - child 6-11 yo	0.000902	0.000044	0.0000118	1.29E-06	4.15E-08	5.02E-09	
Scenario 4 – child 11-13 yo	0.000000	0.000015	0.0000047	0.00E+00	1.39E-08	2.01E-09	
Sum excess risk				**2.99E-06**	**8.65E-08**	**1.21E-08**	**3.09E-06**

Table 30: Exposure assessment and risk characterisation input 'parameters 2019' - content of PAHs: 387 mg/ kg

	exp oral (µg/kg bw/day)	exp dermal (µg/kg bw/day)	exp inh (BaP µg/m3)	Excess risk oral	Excess risk dermal	Excess risk inhalation	Excess risk all routes
Scenario 0 - child 1-2 yo (new!)	0.000000	0.000051	0.0000173	0.00E+00	4.86E-08	7.34E-09	
Scenario 1 - child 2-3 yo	0.002582	0.000049	0.0000173	3.69E-06	4.60E-08	7.34E-09	
Scenario 2 - child 3-6 yo	0.006119	0.000140	0.0000519	8.74E-06	1.33E-07	2.20E-08	
Scenario 3 - child 6-11 yo	0.006589	0.000320	0.0000865	9.41E-06	3.03E-07	3.67E-08	

	exp oral (µg/kg bw/day)	**exp dermal (µg/kg bw/day)**	**exp inh (BaP µg/m3)**	**Excess risk oral**	**Excess risk dermal**	**Excess risk inhalation**	**Excess risk all routes**
Scenario 4 – child 11-13 yo	0.000000	0.000107	0.0000346	0.00E+00	1.01E-07	1.47E-08	
Sum excess risk				**2.18E-05**	**6.32E-07**	**8.80E-08**	**2.26E-05**

ANNEX B - Lifelong exposure Scenario

To determine 'lifelong' exposure for children playing at playground it is assumed that a child plays at playground from the age of 1 up to the age of 13. It is also assumed that the same child has been an outfield player between 4 and 11 years old and has played as an outfield player from age 11 to 18 (performance oriented). The person then continues to play as an adult between 18 and 35 years old (performance oriented) and as a veteran up to the age of 50 (performance oriented). It is also considered that the person plays as an outfield player for 18 years.

Table 31: Input parameters and exposure calculations (ECHA 2019a)

	Age 4-11 Child	**Age 11-18 Child Perf. Oriented**	**Adults 18-35 Perf. Oriented**	**Veteran 35-50**	**Professional outfield player**
General					
Body weight (kg)	15.7	44.8	68.8	68.8	68.8
Frequency (days/week)	2/7	5/7	5/7	2/7	2/7
Frequency (months/year; oral and inhalation)	7/12	10/12	10/12	10/12	10/12
Frequency (months/year; dermal)	7/12	7/12	7/12	7/12	7/12
Duration hours/day	1.5	1.5	2	2	4
Oral exposure					
Oral amount ingested (g)	0.09	0.05	0.05	0.05	0.05
Migration (fraction)	0.09	0.09	0.09	0.09	0.09
Dermal exposure					
Dermal amount contacted (g)	1	3.3	6	6	6
Migration (fraction)	0.0005	0.0005	0.0005	0.0005	0.0005
Inhalation exposure					
PM10 – rubber dust ($\mu g/m^3$)	12	12	12	12	12
Fraction BaP in REACH-8 PAHs*	0.15	0.15	0.15	0.15	0.15

The lifelong exposure is determined by summing up average exposure for each scenario (already based on 70 years' exposure).

Table 32 and Table 33 below reports the lifelong oral, dermal and inhalation exposure values and risks for each contributing scenario developed by ECHA for playgrounds and domestic applications.

Table 32: Lifelong exposure and risk for children playing at playground (PAH content 20 mg/kg)

Contributing scenario (ECHA 2023) playgrounds	**Oral exposure estimate (µg/kg bw/d)**	**Dermal exposure estimate (µg/kg bw/d)**	**Inhalation exposure estimate (µg/m³-year BaP)**	**Risk oral**	**Risk dermal**	**Risk inhalation**	**Risk combined**
0 child 1-2	0.000194	3.14E-06	3.70E-06	2.77E-07	2.97E-09	1.57E-09	2.82E-07
1 child 2-3	0.000153	2.99E-06	3.70E-06	2.19E-07	2.83E-09	1.57E-09	2.23E-07
2 child 3-6	0.000363	8.63E-06	1.11E-05	5.19E-07	8.16E-09	4.71E-09	5.32E-07
3 child 6-11	0.000391	1.97E-05	1.85E-05	5.59E-07	1.86E-08	7.84E-09	5.85E-07
4 child 11-13	0.000000	6.60E-06	7.40E-06	0	6.24E-09	3.14E-09	9.38E-09
5 child 4-11	0.000017	1.06E-05	2.63E-06	2.46E-07	1.00E-08	1.11E-09	2.57E-07
7 ch 11-18 PO	0.00012	3.07E-05	9.38E-06	1.71E-07	2.90E-08	3.98E-09	2.04E-07
8 ad 18-35 PO	0.00020	9.34E-05	3.21E-05	2.86E-07	8.84E-08	1.36E-08	3.88E-07
9 vet 35-50	0.00007	3.11E-05	1.07E-05	9.53E-08	2.95E-08	4.54E-09	1.29E-07
W1 Prof OP	0.00024	1.12E-04	7.14E-05	3.43E-07	1.06E-07	3.27E-08	4.82E-07
Total							
Lifelong consumer	0.00175	3.19E-04	2.06E-04	2.71E-06	3.02E-07	7.48E-08	**3.1E-06**

Table 33: Lifelong excess risk table for domestic application (total)

Contributing scenario **Domestic applications** **(ECHA 2023)**	**Risk oral** **Lifelong**	**Risk dermal** **Lifelong**	**Risk inhalation** **Lifelong**	**Risk combined**
PAH 20 mg/kg	2.27×10^{-6}	2.96×10^{-7}	5.75×10^{-8}	**2.62E-06**
PAH 53 mg/kg	4.13×10^{-6}	3.50×10^{-7}	6.50×10^{-8}	**4.54E-06**
PAH 387 mg/kg	2.29×10^{-5}	8.95×10^{-7}	1.41×10^{-7}	**2.40E-05**

ANNEX C - Summary of Internet research on granules and mulches in loose form used in domestic applications conducted by ECHA

Additional internet research was conducted by ECHA on 14. - 16.3.2023 to support the ECHA Investigation on exposure of PAHs to children in the EU.

The purpose was limited to gather updated information since 2019 on availability in the EU consumers' market of rubber granules or mulches in loose form for use in domestic applications such as playgrounds, gardening and landscaping. The research aimed at finding possible online suppliers where consumers from the EU could purchase rubber granules and mulches in loose form and to gather information from them on annual amounts sold the EU and possibly their PAH content. The research aimed only to confirm that an EU consumer market for these products exists, not to provide a full picture of the EU consumer market of rubber granules and mulches, for which a more extensive investigation, not limited to internet suppliers, would be required. For this reason, the investigation focused on information publicly available on the internet in a limited number of EU countries. Result of the research are shown in Table 34.

Method

The search was limited to twelve EU countries (i.e. Belgium, Finland, France, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Spain and Sweden) and the UK. Local Google search engine (in country specific language) was used as searching tool. The search terms used were (in English) "granules" OR "mulches". To translate these terms into different languages, the corresponding terms for "granules" and "mulches" provided in translated versions of the legal text of REACH Regulation were considered. These terms were used in local Google search engine. The search was performed with Microsoft Edge browser v. 112.0.1722.34 (64-bit) in Windows 10 Enterprise environment. The default language was English and location Helsinki. First, both terms were searched using the national Google search engine (see Search term: the official national translation of ECHA Annex XVII Restriction #50 (9 – 14) "granules" OR "mulches" (EN) (https://echa.europa.eu/regulations/reach/legislation) In case no relevant hits were found from the three first result pages, the search was repeated by using the term "mulches" only. Relevant hits were investigated further, when found. Only "rubber" granules and mulches were considered. Various other organic and inorganic gardening mulches and animal food and fertiliser granules were not considered as relevant hits. A number of web-based retailers were contacted by ECHA to gather information on market data and possible knowledge of PAH content of the material supplied (see at the end of the section).

General considerations

International web retailers often operate as a network via national supplier companies, and it is not easy to distinguish them. Several international web retailers operate from non-EU countries such as UK (re-bound.co.uk, thesurfacingstore.co.uk) and US (rubber-granules.com, rubbermulch.com, groundsmartrubbermulch.com). These retailers, offering loose rubber granulate or mulch products to any EU domestic users, were also considered. Some international web retailers offering these products were also found and contacted (amazon.fr, amazon.de, italian.alibaba.com, ebay.co.uk).

Results

The results and details and findings are described in Table 34.

Twenty online suppliers with ability to ship rubber granules and mulches in the EU were found. Twelve of them sell products directly to consumers while eight of these suppliers provide products to industrial or professional customers. Information is provided in all web sites on type of products supplied and possible uses (e.g. infill material for artificial turfs or use in loose form in playgrounds or home gardens). Domestic use is foreseen for all products sold directly to private customers. No information on quantities supplied in the EU by these companies is available.

No relevant hits were found for FR, NL, PT, RO for rubber granules and mulches (as organic pellets and mulches for gardening were excluded).

Several retailers were found from DE, IT and PL . Also virgin rubber products in loose form were found to be available in DE (melos-gmbh.com), ES (changhongsbs.com, tradepartners.es) and PL (kgl.pl, unirubber.com.pl) even if mainly targeted for industrial customers. Certain retailers offered ELT-based recyclate only (genan.eu, re-bound.co.uk, groundsmartrubbermulch.com). The majority of children's playground equipment suppliers in DE (shop.eibe.net), FI (lappset.fi) and SE (unisport.com) offered both rubber articles (such as mats, tiles, safety surfaces) and also rubber mixtures (granules or mulches in loose form) targeted for professional builders of children's playgrounds for housing companies, playgrounds and sports parks (no direct sale to consumers).

Some good practices and alternative materials were found: a DE supplier (genan.eu) stated to use only EU market approved ELT recyclate as their raw material in EU. FI-based unisport.com had developed novel filling materials for synthetic turfs such as sugar cane or olive kernels to replace rubber.

Some products have been found to have particle size lower than 5 mm, fitting into the EU microplastics definition.

The PAH levels of products were typically not published on companies' websites. References to national or international standards on playground surface materials or toy safety were found. Technical product documents or certificates were found as part of the available documentation. ECHA contacted some companies by phone to gather additional information, however no additional information was obtained.

Conclusions

Several national, regional and international suppliers were found for rubber granules and mulches in loose form in the twelve EU countries where the investigation was conducted, including UK and US based and international retailers.

Materials available for supply were made of virgin as well as recycled ELT rubber. Alternative materials to ELT derived rubber granules and mulches are available and offered in the EU market. Examples include olive kernels or sugar cane.

Main applications identified were loose granules for fillings of artificial turfs, use as safety material in playgrounds and for domestic use. Rubber mulch was offered mainly for gardening and landscaping purposes.

The ELT recyclate market is global and the origin of the material supplied can be difficult to trace. References to quality systems and safety standards and product documents or certificates were commonly available.

Particle sizes of some products available on the market can fit into the EU microplastics definition.

ECHA's questions sent to suppliers of rubber granules and mulches in the EU

Dear supplier

ECHA is preparing an investigation report on Polycyclic Aromatic Hydrocarbons (PAHs) in loose rubber granules and mulches used in domestic applications at the request of the European Commission (https://echa.europa.eu/documents/10162/17233/mandate_pahs_children_investigation_en.pdf/25c4ad9a-7061-de70-c218-ca73a68578a7?t=1674032054073).

We have found loose rubber granules and mulches listed in your website, and would like to ask some clarifying questions:

- What is the quantity (in tonnes, also an estimate or a range is fine) of such material that you sell directly for the consumers in the EU?

- What is the quantity (in tonnes, also an estimate or a range is fine) of such material that you sell to retailers in the EU?

- Would you have an overview of the market situation in the EU for such materials being sold to private consumers or to retailers in the EU?

- Would you have compositional information of such materials? In particular, we are interested in the PAH content information.

Search term: the official national translation of ECHA Annex XVII Restriction #50 (9 – 14) “granules” OR “mulches” (EN) (**https://echa.europa.eu/regulations/reach/legislation**)

Table 34: Outcome of the internet searches

Country	Search engine	Date	Search term	Search result links	Loose rubber granules or mulches for domestic use?	Company for contacting	Date of contact	Answer received
BE	www.google.be	5.4.2023	“granules” OR “paillis”	https://www.amazon.fr/NuPlay-Rubber-Nugget-paillage-am%C3%A9nagement/dp/B08LFVWSZL/ref=sr_1_47_mod_primary_new?c=ts&keywords=Paillis&qid=1680696086&s=lawn-garden&sbo=RZvfv%2F%2FHxDF%2BO5021pAnSA%3D%3D&sr=1-47&ts_id=4338596031&th=1	Yes	Amazon.fr website	Not contacted	
BE	www.google.be	5.4.2023	“granulaat” OR “mulch”	https://rubbermulch.com/products/black-unpainted-playsafer-rubber-mulch-75-cubic-ft-pallet-2-000-lbs	Yes	https://www.rubberecycle.com/rubbermulch	17.4.2023	No
DE	www.google.de	14.3.2023	“Granulate” OR “Mulche”	https://www.genan.eu/applications/sport-and-leisure/	Mostly for professionals	www.genan.eu	16.3.2023	No
DE	www.google.de	14.3.2023	“Granulate” OR “Mulche”	Play equipment (eibe.net)	Mostly for professionals	https://www.eibe.net/	16.3.2023	No
DE	www.google.de	14.3.2023	“Granulate” OR “Mulche”	https://www.readytobuild.de/produkte/	Mostly for professionals	https://www.melos-gmbh.com/kontakt/	16.3.2023	No

Country	Search engine	Date	Search term	Search result links	Loose rubber granules or mulches for domestic use?	Company for contacting	Date of contact	Answer received
DE	www.google.de	14.3.2023	"Granulate" OR "mulche"	https://www.amazon.de/s?k=rubber+granulate+filling&crid=CU00U25TR53V&sprefix=rubber+granul%2Caps%2C104&ref=nb_sb_ss_ts-doa-p_1_13 https://www.amazon.de/-/en/Rubberific-Rubber-Mulch-Brown-Bag/dp/B000KZNMM8/ref=sr_1_5?crid=1YJHCA5QIA9VF&keywords=gummimulch&qid=1680699915&sprefix=gummimusch%2Caps%2C87&sr=8-5	Yes, granules Yes, mulches	www.amazon.de	Not contacted	
ES	www.google.es	15.3.2023	"gránulos" OR "mantillos"	https://tradepartners.es/	Yes	https://tradepartners.es/contact-us	16.3.2023	No
ES	www.google.es	15.3.2023	"gránulos" OR "mantillos"	http://www.changhongsbs.com/	In principle; mostly for industrial users	http://www.changhongsbs.com/	16.3.2023	No
FI	www.google.fi	14.3.2023	"rouheet" OR "katteet", sing. "rouhe" OR "kate"	https://www.lappset.fi/Tuotteet/leikkivalineet/kumirouhetuotteet	Yes; mostly final products for professionals	https://www.lappset.fi/Ota-yhteytta/Yhteystiedot	16.3.2023	Yes: no sales directly to customers
FI	www.google.fi	14.3.2023	"rouheet" OR "katteet",	No relevant hits in gardening websites (only organic pellets and mulches)				

Country	Search engine	Date	Search term	Search result links	Loose rubber granules or mulches for domestic use?	Company for contacting	Date of contact	Answer received
			sing. “rouhe” OR “kate”					
FR	www.google.fr	14.3.2023	“granules” OR “paillis”	No relevant hits (only organic pellets and mulches)				
IE	www.google.ie	14.3.2023	“granules” OR “mulches”	https://www.thesurfacingstore.co.uk/product-category/wetpour-wet-pour-surfacing-supplies/	Yes	https://www.thesurfacingstore.co.uk/contact/	Not contacted	
IT	www.google.it	15.3.2023	"granuli" OR "pacciame"	https://www.rubber-granules.com/en/rubber-products/	Yes	info@prismi.it	16.3.2023	No
IT	www.google.it	15.3.2023	"granuli" OR "pacciame"	https://italian.alibaba.com/product-detail/Granules-Mulch-Epdm-Rubber-Recyclable-Colorful-60732958649.html	Yes	https://italian.alibaba.com	16.3.2013	No
NL	www.google.nl	15.3.2023	"granulaat" OR "mulch"	No relevant hits				
PL	www.google.pl	15.3.2023	"granulaty" OR "ścinki"	http://www.kgl.pl/kgl/pl/granulaty/elastomery.html	Mostly for industrial/ professional customers	info@kgl.pl	16.3.2023	No

Country	Search engine	Date	Search term	Search result links	Loose rubber granules or mulches for domestic use?	Company for contacting	Date of contact	Answer received
PL	www.google.pl	15.3.2023	"granulaty" OR "ścinki"	https://www.unirubber.com.pl/pl/granulaty-epdm	Mostly for professionals	unirubber@unirubber.com.pl	16.3.2023	No
PT	www.google.pt	15.3.2023	"granulados" OR "coberturas"	No relevant hits				
RO	www.google.ro	15.3.2023	"granulele" OR "mulci"	No relevant hits				
SE	www.google.se	14.3.2023	"granulat" OR "täckmaterial"	https://www.unisport.com/sv/produkter https://www.unisport.com/sites/default/files/2020-04/fallskydd-gummi-unisport-se.pdf	Mostly for professionals	https://www.unisport.com/sv/kontakt	16.3.2023	No
UK	www.google.co.uk	14.3.2023	"granules" OR "mulches"	https://re-bound.co.uk/product/playsafe-rubber-chippings/	Yes	www.re-bound.co.uk	16.3.2023	No
UK	www.google.co.uk	14.3.2023	"granules" OR "mulches"	https://www.ebay.co.uk/b/Rubber-Chippings/159419/bn_7114069613	Yes	: https://www.ebay.co.uk/help/home	16.3.2023	No
UK	www.google.co.uk	14.3.2023	"granules" OR "mulches"	https://playbark.com/catalog/play-surfaces	Yes	https://playbark.com/contact-us	16.3.2023	No

Country	Search engine	Date	Search term	Search result links	Loose rubber granules or mulches for domestic use?	Company for contacting	Date of contact	Answer received
US	www.google.co.uk	14.3.2023	"granules" OR "mulches"	https://www.groundsmartrubbermulch.com/	Yes	Contact GroundSmart | GroundSmart Rubber Mulch	Not contacted	

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