ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF PITCH, COAL TAR, HIGH TEMPERATURE IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: Pitch, coal tar, high temperature (CTPHT)

IUPAC Name: Pitch, coal tar, high temperature

EC NUMBER: 266-028-2

CAS NUMBER: 65996-93-2

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About the report

This draft report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the substance in articles from various sources. Information is gathered (if available) from authorisations, applications for authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations and substances in articles notifications (in accordance with Article 7(2) of REACH[1] and the Waste Framework Directive (SCIP database[2])) are also investigated. Information on possible uses of the substance in articles that were not identified during the screening phase, can be gathered through a subsequent call for evidence launched via ECHA's website.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this investigation as incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH[3]. For imported articles the incorporation process is carried out in third countries and therefore outside the scope of EU legislation. However, it should be noted that imported articles are within the scope of this investigation. The incorporation is regarded to cover two type of uses[4]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements[5], while only few exemptions are envisaged in case of restrictions. These include manufacture and

[1] Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles.

[2] In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): https://echa.europa.eu/scip.

[3] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564 Note that ECHA will investigate for this report whether applications for authorisation / authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

[4] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

[5] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

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A. Conclusions

A.1 Conclusions based on the assessment

Pitch, coal-tar, high temperature (CTPHT) has been included on the candidate list (13 January 2010; ED/68/2009) and included into Annex XIV of REACH on 14 June 2017 (Commission Regulation (EU) No 2017/999), with a sunset date of 4 October 2020, due to its carcinogenic Cat 1B (Article 57a), Persistent, Bioaccumulative and Toxic (PBT) (Article 57d), and very Persistent and Very Bioaccumulative (vPvB) (Article 57e) properties (specific constituent PAHs (polycyclic aromatic hydrocarbons)[6] were considered relevant to establish the PBT/vPvB properties of CTPHT). Since ECHA's 6th Annex XIV recommendation, the harmonised classification of CTPHT has been amended. Currently CTPHT is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Carcinogenic, Category 1A[7], H350.

ECHA has gathered information on the uses of CTPHT in articles from various sources. This includes information gathered from the submitted applications for authorisation, during the SVHC listing and recommendation for the inclusion of this substance in Annex XIV, uses identified in the REACH registrations, in substances in articles notifications (in accordance with Article 7(2) of REACH and the Waste Framework Directive), and information obtained via various public database searches.

The call for evidence, which took place between 17 September 2021 and 29 October 2021, did not identify any additional uses of the CTPHT in articles placed on the EU market. Additional publications and upcoming publications were brought to the attention of ECHA. In parallel, ECHA conducted a dossiers update screening campaign from August 2021 to January 2022 targeting registrants of Annex XIV substances, for which the sunset date and latest application date had passed. In this context, ECHA asked registrants of CTPHT to update their registration dossiers. This version of the report takes into account information received from the call for evidence and from updated registrations.

Following an assessment of the available evidence, ECHA considers that there are uses of the substance in articles leading to a presence of PAHs that have the potential to lead to human exposure / environmental releases (cf sections B.2 and B.9). CTPHT as well as several PAHs are PBT, vPvB and non-threshold carcinogens for which no threshold can be determined below which exposure would be safe.

The identified uses of CTPHT in articles are summarised in section A.3.1 and described in detail in section B.2. As explained in section B.9., some of these uses may be partially covered by existing restriction entries (e.g. entry 50 and 72), with regards the carcinogenic properties of PAHs contained in CTPHT and hence in articles (if the concentration of these PAHs in the articles exceeds the limit), which is to be addressed via enforcement. Furthermore it is important to note that these entries do not target PBT or vPvB properties and therefore the risks to the environment are not addressed via the existing restrictions.

[6] The PBT assessment of CTPHT focused on the assessment of its PAH-constituents having been identified in concentrations above or equal to 0.1 %, and therefore goes beyond the 8 PAHS listed in the entry 50 of Annex XVII of REACH.

[7] Carcinogenic properties concluded with human studies for Carc. 1A, vs with animal studies for Carc. 1B.

Following the screening of uses in articles under REACH Article 69(2), ECHA identified a risk for the environmnent which is not adequately controlled in clay targets for shooting, and already submitted a restriction proposal for that use, targeting substances (CTPHT and other substances) containing PAHs in clay targets for shooting.

Regarding the other uses in articles, ECHA concludes that risk cannot be excluded due to the potential presence in articles and the non-threshold nature of hazards (see sections B.9 and B.10). As detailed in section D, ECHA is of the view that further examination of the risks from the presence of polycyclic aromatic hydrocarbons (PAHs) in other articles than clay targets should be considered as part of a larger investigation to assess the risks of PAHs in articles in general, with concerns to human health and the environment (carcinogenicity, PBT, vPvB). If risks are not minimised, a restriction proposal targeting PAHs could be initiated by the European Commission as such restriction would go beyond the provisions of Article 69(2).

Depending on the outcome of the investigation as proposed above, an Annex XV dossier for restriction may be prepared taking into account the emerging priorities in the Restriction Roadmap[8].

ECHA also notes that there are uses of CTPHT in the EU which are in the scope of authorisation but for which no applications have been submitted, as industry consider them out of scope. These uses cannot be subjected to new restrictions according to Article 58(5). It is in the remits of National Enforcement Authorities to ensure that REACH obligations regarding authorisation of uses of CTPHT in the EU are respected (see section A.3.2).

A.2 Targeting

This report under Article 69(2) is targeted at the risk from uses of CTPHT from articles throughout their lifecycle (including the waste stage) and whether or not such uses should be restricted. The report is focused on both human health and environmental hazards due to which the substance is placed on the Annex XIV. Other hazards are not taken into account in this report.

A.3 Summary of the justification

A.3.1 Identified uses, hazard, exposure / emissions and risk

Information on uses in articles

At the latest application date (4 April 2019), a total of eight applications for authorisation had been submitted to ECHA, asking for the authorisation of three different uses: formulations for intermediate uses only, industrial use of CTPHT in the precursor matrix of carbon parts in rocket launchers, and binder in the manufacture of clay targets for sports shooting. The first ones have been granted authorisations, but the authorisation for the use in clay targets has been refused.

As of 1 June 2022, CTPHT is registered at 100 000 - 1 000 000 tonnes per annum and there are 22 active registrations, which report the following uses in articles: clay targets with subsequent professional and consumer uses[9], production of carbon articles, production of refractory articles,

[8] Available at: https://ec.europa.eu/docsroom/documents/49734. Work ongoing in PetCo. Scope to be further clarified taking into account the need for data generation, CLH, SVHC-identification or candidate listing.

[9] Although the authorisation for this use has not been granted by the Commission (decisions applicable from 16 March 2022 - https://eur-lex.europa.eu/legal-

production of some types of electrodes, widespread uses by professionals of paints, coatings, adhesives, sealants and waterproofing materials containing CTPHT with possible incorporation into/onto articles. Other registered uses are not in the scope of this Article 69(2) screening work as the end-products are not articles (use of CTPHT to produce some types of electrodes, use as fuel) or are intermediate uses which do not result in the production on articles (production of active carbon and carbon black).

In addition three substances in articles notifications under Article 7(2) of REACH (SiA notifications) were received and refer to uses in clay targets, refractory material and graphite material.

Uses submitted to ECHA under Article 9(1)(i) of the Waste Framework Directive (so-called SCIP Submissions) are, however, bringing new insight on potential uses not identified from other sources of information. This include uses in materials such as polyethylene, rubber and elastomers, subsequently incorporated into articles.

In summary, articles that are or may be produced with CTPHT, and contain or may contain CTPHT or PAHs (which are the constituents of CTPHT underpinning its risks), are the following:

- clay targets (addressed in a separate Annex XV report[10]),
- articles onto/into which paints, coatings, sealants, adhesives and waterproofing materials are applied or incorporated (e.g. glass fiber felts used for roofing, photographic objective lenses),
- some refractory products such as bricks, and functional articles made of refractory material,
- certain types of electrodes,
- carbon/graphite articles,
- articles made of LDPE (low density polyethylene) such as synthetic textiles (tents, bags), parts of electrical machines and apparatus (lamps),
- articles made of rubber and elastomers materials (rubber conveyor belts),
- hand tools, clocks/watches, golf clubs (addressed in Annex XVII – entry 50)

Some of these uses are partially covered by existing restriction entries (e.g. entry 50 – uses in plastic and rubber that come into direct as well as prolonged or short-term repetitive contact with the human skin – and 72 – uses in textile), with regards the carcinogenic properties of PAHs contained in CTPHT and hence in articles; however these entries do not target PBT or vPvB properties.

These screened uses are in line with uses indicated in the European Union risk assessment report for coal tar pitch, high temperature (EU RAR, 2008, ECHA, 2009a) and information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV (ECHA, 2015a).

As the sunset date for CTPHT has passed, only a limited number of uses are still allowed in the EU. These are uses for which an authorisation has been granted and uses that are exempted

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content/EN/TXT/PDF/?uri=CELEX:52022XC0323(03)&from=EN and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323(02)&from=EN), 14 registrants still report this use as of 1 June 2022, and only 3 have removed it from their registrations.

[10] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e186716202.

from authorisation. In the event they lead to the presence of the substance in imported articles, these uses are relevant for this report.

Information on hazards

CTPHT is included in Annex XIV based on its carcinogenic, persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties according to Article 57. Other endpoints are not relevant for this report.

ECHA (2009b) concluded that CTPHT is a substance containing at least 5 to 10 % of polycyclic aromatic hydrocarbon (PAH)-constituents with vPvB and PBT properties. ECHA (2009b) stressed that while the PBT assessment relied only on the PAH-constituents of CTPHT with a concentration ≥0.1 %, it should be considered that residual constituents of CTPHT may have a structure similar to the selected PAHs and that fractions of these residual constituents may have PBT or vPvB properties as well.

CTPHT is considered to be a genotoxic carcinogen. No threshold can be determined below which exposure would be safe. Lung, bladder and skin cancers are identified as the key cancer risk endpoints for exposure to CTPHT, these are the cancers for which data specific to CTPHT exposures exist from animal studies and industrial epidemiology (ECHA, 2018). CTPHT has been identified as SVHC for its carcinogenic properties on the basis of the existing harmonised classification of the substance (ECHA, 2009b). Many PAHs present in CTPHT are themselves considered as genotoxic carcinogens.

Information on emissions/release/exposure

The hazardous properties of CTPHT are due to the presence of PAHs in CTPHT. Therefore, the content of PAHs in CTPHT and thus in articles, and the emissions of PAHs from the service life of articles and exposure to PAHs, are underpinning the risks.

PAHs are not covalently bound to the materials. They can be released from articles during their service life and when articles are disposed of and treated as waste. This leads to releases to the environment and exposure of workers, consumers and general population via the environment.

Based on available information, there can be exposure and releases from articles made of polymers (e.g. rubber, elastomer, polyethylene) and/or incorporating CTPHT-based paints, coatings, sealants, adhesives and waterproofing materials.

Characterisation of risk

As no safe threshold limit can be established, it is considered that any presence of CTPHT (and PAHs due to the use of CTPHT), in articles made of polymers (e.g. rubber, elastomer, polyethylene) and/or incorporating paints, coatings, sealants, adhesives and waterproofing materials, potentially poses a risk during the service life of the articles and/or their disposal as waste.

When considering risks to human health and the environment due to PAHs in articles, these are not limited to articles made with CTPHT, but are also relevant for articles, including articles not listed above, produced using other PAH-containing substances.

A.3.2 Justification that action is required on a Union-wide basis

As no safe threshold limit can be established, it is considered that any presence of CTPHT and PAHs due to the use of CTPHT in articles, not already regulated under authorisation and other legislations, potentially poses a risk during the service life of the articles and/or their disposal as waste, and should be further investigated.

ECHA is of the view that further examination of the risks from the presence of PAHs from the use of CTPHT in articles should be considered as part of a larger investigation to address risks of PAHs in articles, with concerns to human health and the environment (carcinogenicity, PBT, vPvB). Such an investigation should address the presence of PAHs from CTPHT and from other substances in all articles, including all articles containing PAHs not listed in A.3.1. and not yet regulated.

ECHA also notes that there are uses of CTPHT in the EU which are in the scope of authorisation but for which no applications have been submitted, as industry consider them out of scope (e.g. refractory articles such as bricks, functional articles produced with refractory materials such as sliding gates for metal production, carbon/graphite articles, some types of electrodes when their chemical composition does not play a role in their functionality, i.e. when the carbon is not chemically consumed during the use of the electrodes). The incorporation of CTPHT into articles in the EU cannot be subjected to new restrictions according to Article 58(5). It is in the remits of National Enforcement Authorities to ensure that REACH obligations regarding authorisation of uses of CTPHT in the EU are respected.

A.3.3 Justification that the proposed restriction is the most appropriate Union-wide measure

Not relevant, as no restriction is proposed at present.

B. Information on hazard and risk

B.1 Identity of the substance and physical and chemical properties

B.1.1 Name and other identifiers of the substance

Chemical name:	Pitch, coal tar, high-temp.
EC Number:	266-028-2
CAS Number:	65996-93-2
IUPAC Names:	Coal Tar Pitch, High temperature; Pitch, coal tar, high temperature; Coal tar pitch; CTPHT

B.1.2 Composition of the substance

Chemical name:	Pitch, coal tar, high-temp.
EC Number:	266-028-2
CAS Number:	65996-93-2
IUPAC Names:	Coal Tar Pitch, High temperature; Pitch, coal tar, high temperature; Coal tar pitch; CTPHT
Molecular formula:	Not applicable
Structural formula:	Not applicable
Molecular weight:	Not applicable
Typical proportion %:	Not applicable
Concentration range %:	Not applicable

CTPHT is a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials) characterised by a variable and high content of polycyclic aromatic hydrocarbons (PAHs), heterocyclic compounds and benzocarbazoles. It is the residue from the distillation of high temperature coal tar (CAS no. 65996-89-6) under vacuum in closed systems. The EINECS description is as follows: “The residue from the distillation of high temperature coal tar. A black solid with an approximate softening point from 30°C to 180°C. Composed primarily of a complex mixture of three or more membered condensed ring aromatic hydrocarbons”. The composition includes a large variety of polynuclear aromatic constituents, including heterocyclic derivatives. Its exact composition varies due to its variable and complex nature, as well as due to variations in the distillation temperature. Based on registration data, PAHs with more than 4 rings can be present at a concentration above 1 %. More than 80 % of the substance is composed of non-volatile multiple membered condensed ring aromatic hydrocarbons / toluene insoluble resins that present a very complex UVCB composition and a very high number of rings. CTPHTs of different composition may be named with different synonyms hinting to their intended use, e.g. binder pitch or impregnating pitch (ECHA, 2009b).

In the European Union risk assessment report on CTPHT (EU RAR, 2008), the EPA 16 homocyclic PAHs are regarded as being representative for the PAH emissions from CTPHT and the risk assessment is based on exposure and effect data available for these PAHs. When the Annex XV report for identification of substance of very high concern (SVHC) (ECHA, 2009a) was compiled, information on the content of the 16 indicator PAHs and other organic constituents in CTPHT was available for CTPHT either used for impregnating or for binding. As the main use of CTPHT was as binder pitch for the production of anodes and electrodes, the data on composition available for binder pitch (Annex 1) was therefore chosen as reference for the content of PAHs in the substance (ECHA, 2009b). The twelve following PAHs were considered relevant to establish the PBT properties of CTPHT: anthracene, phenanthrene, fluoranthene, pyrene, benz(a)anthracene, chrysene, benzo(a)pyrene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(ghi)perylene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd)pyrene.

The composition of these twelve PAHs in the 'European Composite Sample' is given in Table 1, as provided in the registrations and the applications for authorisations.

Table 1: Concentration of 12 PAHs in the European Composite Sample of CTPHT (Registrations and Applications for Authorisation 0148-01 and 0149-01)

PAH	EINECS No.	CAS No.	Molecular Formula	Molecular Weight	Concentration (%)
Anthracene	204-371-1	120-12-7	$C_{14}H_{10}$	178.23	0.057
Phenanthrene	201-581-5	85-01-8	$C_{14}H_{10}$	178.23	0.302
Fluoranthene	205-912-4	206-44-0	$C_{16}H_{10}$	202.25	0.835
Pyrene	204-927-3	129-00-0	$C_{16}H_{10}$	202.25	0.726
Benzo[*a*]anthracene	200-280-6	56-55-3	$C_{18}H_{12}$	228.29	0.599
Chrysene	205-923-4	218-01-9	$C_{18}H_{12}$	228.29	0.835
Benzo[*a*]pyrene	200-028-5	50-32-8	$C_{20}H_{12}$	252.31	0.873
Benzo[*b*]fluoranthene	205-911-9	205-99-2	$C_{20}H_{12}$	252.31	1.125
Benzo[*k*]fluoranthene	205-916-6	207-08-9	$C_{20}H_{12}$	252.31	0.393
Benzo[*ghi*]perylene	205-883-8	191-24-2	$C_{22}H_{12}$	276.33	0.55
Dibenzo[*a,h*]anthracene	200-181-8	53-70-3	$C_{22}H_{14}$	278.35	0.078
Indeno[1,2,3*cd*]pyrene	205-893-2	193-39-5	$C_{22}H_{12}$	276.33	0.618
Sum 12 PAHs					**7.0**

B.1.3 Physicochemical properties

Table 2: Physicochemical properties of CTPHT (ECHA, 2009b)		
REACH ref Annex	**Property**	**Value**
VII, 7.1	Physical state at 20 C and 101.3 kPa	Black Solid
VII, 7.2	Melting / freezing point	Melting point approx[11]. 116 °C for the composite sample, typically > 65 °C
VII, 7.3	Boiling point at 1013 hPa	>360 °C
VII, 7.8	Density	Typical range between 1.15 to 1.4 g/cm3
VII, 7.5	Vapour pressure (Pa)	<10 (at 20 °C) <1000 (at 200 °C)
VII, 7.8	Partition coeffient (NB: not applicable to coal-tar pitch, but to single PAHs)	6.13 (at 25°C)
VII, 7.7	Water solubility (NB: not applicable to coal-tar pitch, but to single PAHs)	0.002 mg/L (at 20°C)
VII, 7.9	Flash point	Flash point at 101 325 Pa: 200 °C
VII, 7.12	Autoflammability/Self-ignition temperature	at 101 325 Pa: 560 °C

B.1.4 Justification for grouping

ECHA proposes that further examination of the risks from the presence of PAHs from the use of CTPHT in articles should be considered as part of a larger investigation to address risks of PAHs in articles, with concerns to human health and the environment (carcinogenicity, PBT, vPvB). Risks to human health and the environment due to PAHs in articles are not limited to articles made with CTPHT, but are also relevant for articles made with other PAH-containing substances. In particular, Anthracene oil (EC 292-602-7) is also included in Annex XIV and an Annex XV report in accordance with Article 69(2) of REACH has been developed, with the same conclusion. The proposed investigation should also consider other PAH-containing substances than CTPHT and Anthracene oil.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

CTPHT is the residue from the distillation of high temperature coal tar. In 2009, coal tar distillation occurred at 11 manufacturing sites, owned by seven different companies, in nine EU Member States (ECHA, 2009a). These sites had a total distillation capacity of around 2 475 kilotonnes per year (kt/y). The actual manufacture (distillation) of coal tar derivatives was however quoted around 2 000 kt/y (ECHA, 2009a). With regard to the import/export balance of CTPHT, the EU Risk Assessment Report (EU RAR, 2008) notes that in 2004 import and export of CTPHT from/into EU were respectively around 92 kt/y and 355 kt/y; the RAR estimated the total EU use of CTPHT to be around 554 kt/y (EU RAR, 2008). According to the Chemical Data

[11] Softening range; Internal communication, Coal Chemicals Sector Group/CEFIC 2006 (cited in ECHA, 2009a)

Reporting (CDR) data submitted to US-EPA under the Toxic Substances Control Act (TSCA), the volume exported out of the USA was 19,240 tonnes in 2014 (CDR, 2014). According to ECHA (2015a) information on the registration data, the amount of CTPHT manufactured and/or imported into the EU was in the lower part of the range 1 000 000 - 10 000 000 t/y. A small share of the tonnage was reported as being exported outside the EU (ECHA, 2015a). One sector association commenting during the public consultation on the draft 6th recommendation (ECHA, 2015a, ComRef, 2015) indicates an actual tonnage manufactured and/or imported in EU of approximately 800 000 – 900 000 t/y, of which 320 000 t are directly exported (data collection from year 2013). Furthermore, according to ECHA (2015a) the volume for uses in the scope of authorisation (e.g. formulation of mixtures, uses in clay targets, uses in mixtures for corrosion protection, uses in metallurgic smelting, uses in refractory products) was estimated to be >10 000 t/y. Data in SPIN database show a decline in the total tonnage from early 2000 to 2017 (Denmark), 2018 (Finland) and 2019 (Sweden); however in Norway the declared tonnage has been increasing up to ~ 200 000 tonnes in 2018.

According to current registration information as of 1 June 2022, CTPHT is registered at 100 000 - 1 000 000 tonnes per year[12].

Based on the applications for authorisations, the tonnage for uses in the scope of authorisation is between 57 008 and 744 008 t/y.

Manufacturing and import may continue today for authorised uses and uses exempted from authorisation or for export.

B.2.2 Uses in articles

B.2.2.1 Information on uses

Applications for authorisation

There are eight applications for authorisation submitted to ECHA for CTPHT covering three different uses (Table 3). Seven were still pending authorisation when the call for evidence on this report was launched, and decisions have been made in March 2022. Therefore, this section has been updated. At present, six authorisation have been granted by the Commission and two have been denied.

Article service life has been assessed in three applications, for the use of CTPHT in the production of clay targets and the production of highly resistant carbon parts of aerospace launchers. CTPHT is present in clay targets in high concentration (about 30%), but no CTPHT remains in the carbon parts of aerospace launchers.

Five out of eight applications have been received for the “use of CTPHT for formulation of mixtures, for various industrial uses”, which cover the formulation of mixtures for the production of electrodes, carbon black, activated carbon, ‘special tar mixtures’ exported outside the EEA, and (as a future use) ‘other mixtures’, which are unspecified. All the applicants for this use of CTPHT in mixtures consider that downstream uses of these mixtures are intermediate uses and are therefore exempted from authorisation. No article service life is therefore taken into account by the applicants.

[12] https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/15300/1 (accessed 1 June 2022)

Table 3: Information on Applications for Authorisation for CTPHT[13]					
Use applied for by the applicants	**Tonnage (t/y)**	**Emissions to the environment (per year)**	**Status of the authorisation and remarks**		**ID**
Industrial use of pitch, coal tar, high temp. as precursor of carbon matrix in the manufacturing of thermally and thermo-mechanically highly loaded carbon/carbon parts including nozzle throats and other critical carbon-carbon composite parts, resistant to very harsh erosion conditions, and very high temperature ranges, dedicated to high-performance civilian and military aerospace launchers	8.1	1.62 kg (16 PAHs)	Authorisation granted (REACH/21/1/0) on 13 January 2021 Date of expiry of review period: 4 October 2032	Final articles contain only trace amount of CTPHT according to applicants; no risk related to articles service life identified by RAC	0144-01
Use of CTPHT for manufacture of formulations for various industrial uses[14] (5 applications)	1 000 – 3 000	0.297 kg (9 PAHs)	Authorisation partially granted (REACH/22/10/0) on 16 March 2022	Authorisation granted for the use of CTPht in formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation requirement set out in Regulation (EC) No 1907/2006 Date of expiry of review period: 04 October 2032 No uses in articles expected	0149-01
	3 000 - 16 000	6.17×10^{-3} kg (9 PAHs)*	Authorisation partially granted (REACH/22/11/0) on 16 March 2022		0150-01
	40 000 – 400 000	1.9 kg (9 PAHs)*	Authorisation partially granted (REACH/22/13/0) on 17 March 2022		0151-01
	10 000 - 300 000	0.993 kg (9 PAHs)*	Authorisation partially granted (REACH/22/14/0) on 16 March 2022		0152-01
	1 000 – 5 000	0.8 kg (9 PAHs)*	Authorisation partially granted (REACH/22/12/0) on 16 March 2022		0153-01
Use of CTPHT as a binder in the manufacture of clay targets (2 applications)	For each application : 1 000 - 10 000	For each application : 70-700 tonnes	Authorisations refused on 16 March 2022	Risk identified for the service life of articles: restriction foreseen for the use in imported articles and the use of alternatives to CTPHT in a separate Annex XV dossier	0147-01, 0148-01

[13] Search done 1 June 2022: https://ec.europa.eu/docsroom/documents/49714 and https://echa.europa.eu/applications-for-authorisation-previous-consultations

[14] Formulation of mixtures for the production of electrode (graphite electrodes pitch, electrode used in the aluminium industry), carbon black production (carbon black feedstock (CBO), Söderberg pitches), and activated carbon, formulation of 'special tar mixtures' exported outside the EEA, formulation of 'other mixtures'.

* releases include PAHs from CTPHT and anthracene oil

As a general observation, it should be noted that for all substances the 'manufacturing' lifecycle stage (including synthesis, transfer and storage steps) is out of the scope of authorisation; furthermore a substance may also be manufactured for uses exempted from authorisation (ECHA, 2015a), such as use as on-site and transported isolated intermediate (Article 2(8) of REACH), use in fuels (Article 56(4)(c)(d)) and export of the substance. Thus a number of uses are not subject to authorisation.

The Member State Committee (ECHA, 2015b) reminded companies that it is their responsibility to assess whether their uses of CTPHT are in the scope of authorisation and if there is a need to submit applications for authorisation.

It should be noted, in addition, that there are discrepancies between the uses included in applications for authorisations and information provided in registration dossiers (see below) with regards with the relevance of intermediate status and service life.

Substance in articles notifications

Three Substance in Articles (SiA) notifications[15] have been made under Article 7(2) for CTPHT:

- nozzle as flow controller of melted iron in steel making process (notified in 2011),
- impregnation of pre-baked shapes in graphite industry (notified in 2012),
- clay targets (notified in 2015).

The SiA notification for a nozzle used in steel making process reports that the article contains low concentration of CTPHT. Information in the SiA notifications indicates that the production process of a nozzle is similar to those of other products, such as sliding gates. As the production process of these products entails steps like machining and assembling, exposure to workers and to the environment cannot be excluded if residual CTPHT is present in the articles.

There are still uncertainties regarding the nature of the article(s) covered by the notification of impregnation of pre-baked shapes in graphite industry and the content of CTPHT. However, graphite as such is not of concern as graphitization occurs at very elevated temperature (> 2200°C) and, at these temperatures, all carbon-containing substances (including CTPHT) are converted into graphite (CAS No. 7782-42-5) (ECHA, 2009a).

The use in clay targets is registered and covered by applications for authorisation. Such use is addressed in a separate Annex XV report[10].

Submissions under the Waste Framework Directive (SCIP)

According to SCIP submissions[16], CTPHT is likely to be found in petroleum resins, LDPE (low density polyethylene), and in rubber and elastomers materials and specific articles reported made of such materials.

CTPHT presence was reported in: rubber conveyor belts (most likely in the rubber belt itself); as petroleum resins used for optical lenses (e.g. as adhesives/lubricant, including for lenses

[15] https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table (December 2019)

[16] Information extracted on 11 June 2021. Since then a large number of new submissions have been made.

contained in consumer photographic cameras); parts/accessories of golf clubs and other golf equipment (most likely the rubber/polymeric parts accessories, such as handles/grips); synthetic textiles (i.e. sacks and bags made out of LDPE and tents made out of synthetic fibres); parts of hand tools (i.e. glaziers' diamonds); parts of electrical machines and apparatus made of polyethylene (in particular reported uses in parts of lamps); and in parts of precision instruments used for precision measurements.

These uses are different than registered uses. Other articles and materials may be relevant, as the SCIP database is continuously updated.

Uses identified before the inclusion of CTPHT in Annex XIV

Table 4 and Figure 1 below provide information on uses and tonnages before the inclusion of the substance in Annex XIV on 14 June 2017. Although uses and tonnages are expected to have changed since then, it could still give indication on potential uses of articles, either imported articles or uses not covered by Application for Authorisation.

Table 4 summarises the uses according to information received from the public consultation on the 6th draft Recommendation (ComRef, 2015). It gives rather recent information of the uses and tonnages of CTPHT in the European markets.

Table 4: Summary of CTPHT uses and tonnage per use based on comments received during the public consultation on the 6th draft Recommendation (ComRef, 2015)

Uses	Volume (t/y)
Intermediate uses	
Manufacture of 'pitch coke', correctly named 'Coke (coal tar), high temp.pitch (CAS 140203-12-9) in the following sectors/for the following processes - In the aluminium industry: in the production of binder for prebake anodes , for cathodes / cathodes ramming paste, for Söderberg electrodes; in the production of collar paste for prebake anodes - In the steel industry: in the production of binder for graphite electrodes - In the metallurgical processes, CaC2: in the production of binder for prebake electrodes, for Söderberg electrodes, for shaped refractories, for furnace lining paste, for top hole paste and runner mix - In the carbon and graphite industry: in the production of carbon/graphite specialities - In the active carbon supply chain: in the production of binder for activated carbon - In the refractory supply chain: in the production of binder for carbonised refractory products - In the production of impregnating agent for graphite electrodes, graphite electrodes connectors (nipples) and for refractories	510,000
Manufacture of carbon black (CAS 1333-86-4)	40,000
Manufacture of other substances	40,000
Other use exempted from authorisation	
Use as fuel	1,000
Non intermediate uses	
Binder for clay targets	15,000
Binder for airport driveway repair work Heavy-duty corrosion protection	Ca. 2,000

The mass flow diagram of the uses of CTPHT in Figure 1 represents slightly older data in terms of uses and tonnages but provides a descriptive breakdown of recent applications of CTPHT (ECHA, 2009a).

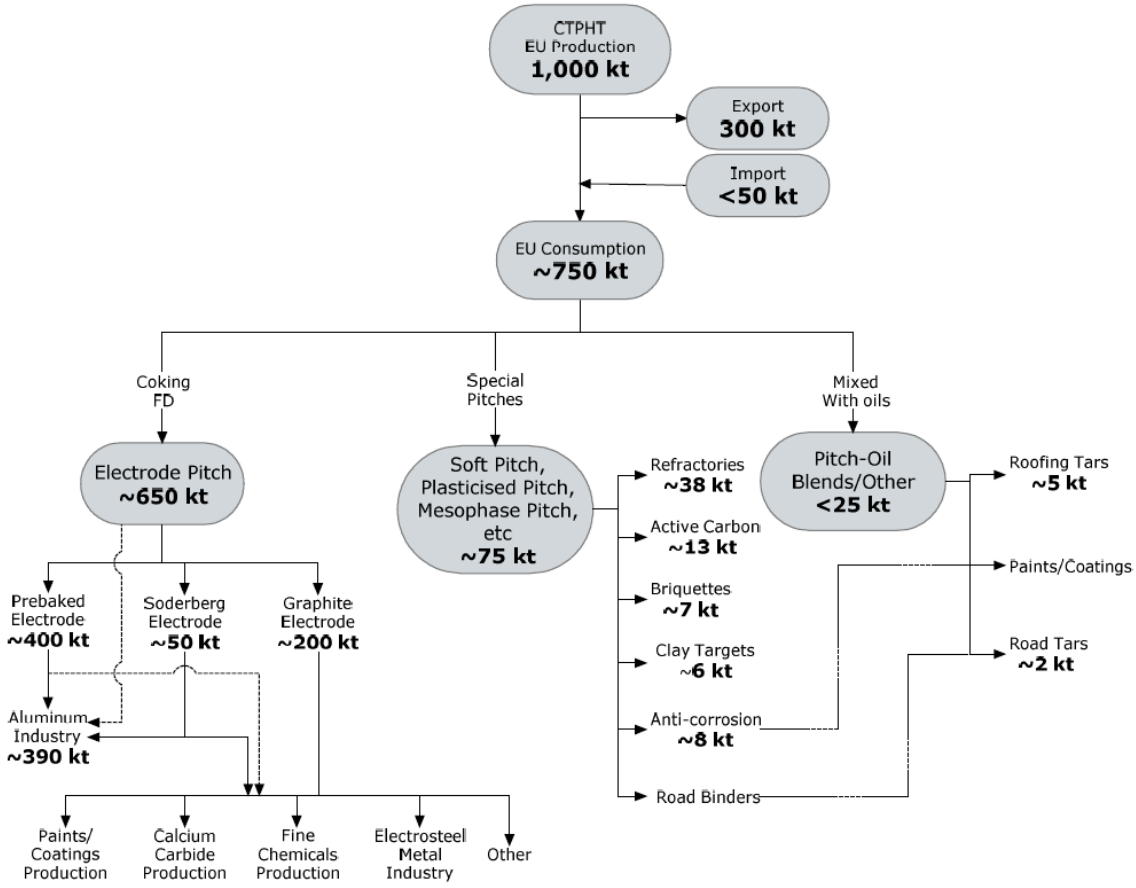

Figure 1: Mass flow diagram of the uses of CTPHT (ECHA, 2009a)

As seen in Figure 1 and Table 4, the main use of CTPHT is as binding agent in the **production of electrodes** (whether anodes, cathodes or graphite electrodes, containing CTPHT in different amounts) used in the production of primary metals (e.g. aluminium), ferro-alloys, non-ferrous metals, metal alloys, calcium carbide and silicon carbide (Annex XV report, 2009, ECHA, 2015a). In ComRef (2015) aluminium industry was mentioned as the biggest consumer of the CTPHT volume (60-70 %). Coke electrodes used in aluminium industry are not considered as articles[17] as per REACH-definition and hence are not in the scope of this screening report. Similar considerations may apply to same type of electrodes used in some metal sectors, in particular when the carbon contained in the electrode works also as a reducing agent and it is therefore "chemically consumed" during the process. In ECHA (2009a), it is specified that CTPHT can also be used to produce **specialty carbon and graphite products** (other than electrodes) but the tonnage allocated to this use is accounted together with the amount used to produce carbon and graphite electrodes. Specialty carbon and graphite products are used in many, primarily high temperature, processes including: moulds, furnace parts, seals and brushes, silicon

[17] Q&A 1195 (22/06/2016), available at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1195

manufacture, oil drilling, metallurgical processes, etc. According to the European Carbon and Graphite Association (ECGA, 2016) these latter uses are considered intermediate uses as CTPHT is transformed into pitch coke (CAS No. 140203-12-9, exempted from registration according to Annex V of REACH) in the production process. Pitch coke can be further baked (graphitized) at high temperature (> 2200°C) to produce graphite (CAS No. 7782-42-5).

Based on Figure 1, there are several different downstream uses from special pitches and CTPHT mixed with oil, such as use in refractories, activated carbon, clay targets and products for anti-corrosion protection.

- **Refractories** are materials that maintain sufficient physical and chemical stability to be used for structural purposes in high temperature environments encountered in the process industries. They provide linings for high-temperature furnaces and other processing units or systems, in the sectors of metal, cement, glass production, in the aerospace industry and in the nuclear industry. By definition, they are expected to be able to withstand physical wear, mechanic stress and strain, corrosion by chemical agents and high temperatures (above 500ºC). CTPHT is used as a binder which, when added to a refractory mix, holds the various aggregates and matrix particles together (thereby contributing to the refractory products' strength) in a form that can be handled with minimum breakage. Refractories can be available as articles or mixtures (Annex XV report, 2009, ECHA, 2015a).

- **Activated carbon** are typically used as solid adsorbent materials and can be found in a variety of applications including: air treatment, drinking water treatment, effluent water treatment, food processing, industrial processes (purification and catalysis), medical uses (charcoal cloth, masks), military and industrial respirators and a number of other applications. Activated carbon is also available in special forms such as cloth and fibres (ECHA, 2009a). Pitch-based active carbons are made by pyrolysis of pitch to pure carbon (EU RAR, 2008). The use is regarded as an intermediate use and the final material, which is not considered as an article, does not contain CTPHT anymore (ECHA, 2009a).

- CTPHT is used as a binding agent in **clay targets** (previously known as "clay pigeons") which are designed as flying (saucer-shaped) targets for sports shooters and small game hunters to practice on, or in actual sports. The targets are flung into the air to create moving targets to shoot at; they must, therefore, be able to withstand the stress of transportation and being thrown from traps at very high speeds while also disintegrating readily when hit by a pellet (ECHA, 2009a). Clay targets are made to very exacting specifications with regard to their weight and dimensions and are required to conform to international standards. Clay targets are regarded to be articles.

- CTPHT is used in **coating products for corrosion protection**. For heavy duty corrosion protection and application as sealing compounds, a further increase in the plasticity range is achieved by hot-mixing these pitches with extenders such as finely ground coal, minerals, diatomaceous earth, or fly ash. To meet especially high anti-corrosion requirements, coal tar pitches are combined with polymers. Such pitch-polymer combinations may consist of two-pack systems with epoxy or polyurethane or one-pack systems with other polymers or elastomers. Pitch-based paints is used for various applications such as to protect concrete, steel constructions in industry, hydraulic steel structures, underground pipelines, for instance in the sewerage and effluent sector or in ship building (ECHA, 2009a). Such uses are considered as in the scope of authorisation (ECHA, 2015a).

- CTPHT is or was used as binder in coal **briquettes**, which are combustible fuel materials for domestic use (heating, barbeques) or industrial heating (ECHA, 2009a). Coal tar pitch will be

totally transformed or volatised during the briquettes' production process. It is uncertain if this use still exist as of now. The term "briquette" may also refer to the shape of electrodes (see registrations below). This use would fall within the scope of authorisations as being a use as a mixture. No AfAs were received for this use, and this is outside the scope of this report, as not being a use in articles.

- CTPHT is or was used in **road construction and paving** as a binding/sealing agent. Although bitumen and asphalt are much more commonly used, coal tar pitch coatings are used to provide a protective sealing layer to extend the life and lower maintenance of asphalt pavement. It should be noted that most of the European countries (for instance the Netherlands) have banned the use of coal tar pitch in road construction by law or agreement between trade unions and road building companies (ECHA, 2009a). However CTPHT has special applications such as in airport runways as anti-skid layers (ECHA, 2009a). It is uncertain if these uses still exist as of now, but if they do, they would be in the scope of authorisation. It seems irrelevant to consider imported articles for this use.

- CTPHT is used for **roofing**, as impregnating, coating and adhesive agent, mainly for waterproofing purposes. The traditional coal tar system is a built-up roof that is manufactured on-site, with layers of felts adhered to the roof using hot-applied coal tar pitch. Coal tar pitch acts as the waterproofing agent that protects the roof from the elements, while the felts act as reinforcement (ECHA, 2009a). Such uses would be in the scope of authorisation. It is uncertain if roofing materials in the form of articles containing CTPHT could be imported in the EU, however CTPHT-coated fibers (such as glass fiber felts[18]) used as reinforcement seem to exist.

- ECHA (2009a) also mentions uses in medicinal/cosmetic applications (mixtures).

Information from registrations

As of 1 June 2022, there are 22 active registrations and the following uses are registered for CTPHT[19]:

- **active carbon**: formulation of untempered products, production of tempered active carbon products (life cycle stages: formulation, industrial uses, service life). These uses are reported in 18 active registrations. It should be noted that service life is reported only in registration dossiers that have not been updated since 2010.

- **electrodes used in the aluminium industry, calcium carbide industry, carbon and graphite industry**: formulation of green anodes and cathodes, collar paste, black anodes and cathodes, green pastes (e.g. ramming paste, lining paste, etc.), green Söderberg briquettes, lining blocks, briquettes, production by the prebaked method, production by the Söderberg method), manufacture of carbonised materials (e.g. furnace linings, electrodes including cathodes and anodes) (life cycle stages: manufacture, formulation, industrial uses, service life). These uses are reported in 22 active registrations. It should be noted that service life is reported only in registration dossiers that have not been updated since 2010.

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[18] During the screening for this report, a Material Safety Data Sheet (MSDS) from US (2005) for glass fiber felts containing CTPHT was found. The weight percentage of the substance was reported between 5-10%. The company providing the product has it listed still in their webpages with the aforementioned MSDS. http://www.durapax.com/MSDS_Tar_Coated_Glass_Fiber_Felts_3.pdf (accessed 2 September 2021).

[19] Reviewed 30 April 2021. Only the uses in currently active registrations are reported, although other uses may have existed earlier (for instance, a registration reported a use to produce automobile parts, but is no longer active).

- **carbon black production**: use as feedstock for carbon black production (life cycle stages: formulation, industrial uses, service life). This is a use of CTPHT as a transported isolated intermediate under strictly controlled conditions (Article 18) which in not assessed in the chemical safety reports. This use is reported in 16 active registrations. It should be noted that service life is reported only in registration dossiers that have not been updated since 2010.

- **electro-steel industry, metallurgic smelting industry** (life cycle stages: industrial uses, service life): not much information is available on the details of these uses and the role of CTPHT. The environmental release category (ERC) 5 suggest a use at industrial site leading to inclusion into/onto article; and service life is mentioned. These uses are reported in 20 active registrations. It should be noted that service life is reported only in registration dossiers that have not been updated since 2010.

- **clay targets**: use as a binder in the production of clay targets, service life of clay targets (life cycle stages: formulation, industrial uses, professional uses, consumer uses, service life). This use is reported in 14 active registrations.

- **refractory**: formulation of green shaped and unshaped (dry and castable) refractory products, impregnation of refractory products, production of tempered shaped refractory products, end use of green refractory products (shaped and unshaped) incl. impregnated refractory products (life cycle stages: formulation, industrial uses). These uses are reported in 18 active registrations.

- **fuel, industrial energy production**: use as fuel in industrial heavy diesel engines, use as a liquid fuel, use for industrial energy production (life cycle stages: formulation, industrial uses, service life). These uses are reported in 18 active registrations. It should be noted that service life is reported only in registration dossiers that have not been updated since 2010.

- **paints, coatings, sealants, waterproofing materials, adhesives**: formulation of paints, coatings, sealants and waterproofing materials; industrial use and service-life of paints, coatings, sealants and waterproofing materials; formulation and end use of coatings, paints, and adhesives containing CTPHT; wide-dispersive use of paints, coatings, sealants and waterproofing materials (life cycle stages: formulation, industrial uses, professional uses, service life). The sectors are not specified. These uses are reported in 12 active registrations.

- **formulations for various industrial uses**: manufacture of formulations for various industrial uses, formulation of products from coal tar distillation at production site (life cycle stage: formulation). These uses are reported in 9 active registrations. The registrants claim that the formulations are used as intermediates. One use is specifically dedicated to export of formulations outside EEA for uses as intermediates and biocides.

Information from external databases

Searches were performed in various other databases (Annex 2) in order to identify any information on the substances presence in articles. The findings do not contradict information available from AfAs, notifications and registrations. A few products (sealants, coatings, mastics) are reported in SIRI and CPID databases. SPIN data report a decreasing number of preparations from early 2000 to 2017 (Denmark), 2018 (Finland) and Sweden (2019) with zero preparations in the latest years; 19 preparations including consumer preparations were still declared in Norway in 2018; historical uses reported in SPIN are in line with the registered uses.

B.2.2.2 Conclusions: uses in articles to be considered in this report in accordance with Article 69(2)

First of all, as the sunset date for this substance has passed, only the uses for which an authorisation has been granted and the uses that are exempted from authorisation (use as on-site or transported isolated intermediates (Article 2(8) of REACH), use in fuels (Article 56(4)(c)(d)) of REACH), are allowed). Therefore, several uses identified should have been phased out or substituted since they are not allowed anymore in the EU. ECHA notes that most registrations have not been updated even after the call for evidence and the campaign letter from ECHA and still report uses that are not allowed anymore.

Intermediate uses of CTPHT are out of the scope of Article 69(2) restrictions as they don't lead to the incorporation of CTPHT into/onto articles. However, establishing whether a use of CTPHT is an intermediate use, or is not an intermediate use, is not always obvious. The conclusions are summarised below:

- Intermediate uses (out of scope of this Article 69(2) report):
    - The production of **active carbon** is an intermediate use.
    - The production of **carbon black** is a use as transported isolated intermediate under strictly controlled condition (SCC).
    - Some registrations and applications for authorisation also refer to the formulation of **unspecified mixtures**, which are then used as intermediates. It is uncertain what these mixtures are used for, but during the processing of the applications for authorisation, no use of articles produced from these mixtures has been identified. Authorisation have been granted for the formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation requirement set out in Regulation (EC) No 1907/2006.
- Non-intermediate uses:
    - The production of **clay targets** is not authorised in the EU, and the use of imported clay targets is addressed in a separate Annex XV report[10].
    - **Paints, coatings, sealants, waterproofing materials and adhesives** are mixtures which could be applied onto articles or used in the production of articles, e.g. to bind pieces together. Uses of the mixtures (e.g. to protect concrete, steel, pipelines, or as a road sealant or to waterproof roofs) and incorporation into/onto articles are not allowed anymore in the EU since no applications for authorisation were submitted or authorisation granted. Information gathered suggest that glass fiber felt for roofing, as well as various complex articles (e.g. optical lenses containing adhesive), are available and therefore import and use in the EU of articles cannot be excluded.
    - CTPHT is also used to produce **specialty carbon and graphite products**. Impregnation and baking lead to the production of carbon articles, which can be subsequently graphitized at elevated temperature. Import and use of articles in the EU cannot be excluded based on available information.
    - Some additional uses reported under the Waste Framework Directive are of interest for this screening: rubber conveyor belts, parts/accessories of golf clubs and other

golf equipment (most likely the rubber/polymeric parts accessories, such as handles/grips), parts of hand tools, synthetic textiles (i.e. sacks and bags made out of LDPE and tents made out of synthetic fibres); parts of electrical machines and apparatus made of polyethylene (in particular reported uses in parts of lamps); parts of precision instruments used for precision measurements.

- The uses in fuels and medicinal/cosmetic applications are not relevant in the Article 69(2) report, as they are not articles.

- Uses that can be intermediate or non-intermediate, depending on whether the produced item is a substance/mixture (i.e. intermediate use) or an article (i.e. non intermediate use), and depending on whether the mixing of CTPHT and filler is carried out on the same site (if not on the same site, this may indicate that the mixing step is not performed to facilitate/ensure proper chemical processing in the synthesis, in which case this is not an intermediate use):

    - ECHA considers that **electrodes** for use in some metal industries made with CTPHT are not articles but substances, and hence the use of CTPHT to produce these electrodes is an intermediate use. This is the case when the chemical composition of the electrode is more important than its surface, shape or design; the carbon contained in the electrode works as a reducing agent and it is therefore "chemically" consumed during its use. Although these electrodes have a certain shape, the same functionality could be obtained using a different shape, surface and design (RCOM 2009, Q&A 1195[17]). On the contrary, when the surface, shape or design of the electrode is more important than its chemical composition and the carbon is not consumed upon use, it is an articles and thus the production of such electrodes is subject to authorisation. No applications for authorisation were submitted or authorisations granted for the use of CTPHT to produce electrodes. Still, import of such electrodes and use in the EU cannot be excluded[20].

    - The production of unshaped refractory products result in a substance/mixture being produced and is an intermediate use. On the contrary, the production of **refractory articles** (e.g bricks) and functional articles made of refractory material (such as sliding gates, nozzles), is not regarded as an intermediate use according to the Commission and ECHA (ComRef, 2015). Although CTPHT is transformed in the production process, the outcome of the process is an article and not a new substance. The interpretation has earlier been challenged by the industry claiming that all refractory products are substances under REACH. It is therefore subject to authorisation. Only one application has been received and authorisation granted in this category of uses. ECHA is not assessing the *incorporation* of CTPHT in refractory articles in this Article 69(2) screening report as this is addressed by the authorisation process, where, in the absence of a granted authorisation for this use, it is no longer allowed in the EU after the sunset date, and cannot be subjected to new restrictions according to Article 58(5). However, the *use* of refractory articles is in the scope of this report (see section B.9). Import of such refractory articles and use in the EU cannot be excluded.

[20] Eg: https://www.amazon.com/ESICO-TRITON-R10397-CARBON-ELECTRODES/dp/B005TBQAJA/ref=sr_1_6?keywords=carbon+electrode&qid=1654175823&sr=8-6

Table 5 summarises the status of the various uses and their relevance within the scope of Article 69(2).

Table 5: Summary of the uses of CTPHT					
Uses	**Registration status**	**Authorisation status**	**SiA notification**	**SCIP submissions**	**Use in articles**
Clay targets	Registered (with service life)	Authorisations **not** granted	Yes	No	Yes (separate Annex XV report) [10]
Paints, coatings, sealants, adhesives and waterproofing materials[21]	Registered (with service life)	No AfA submitted	No	Yes (adhesive)	Yes
Refractory products (including in metallurgic smelting industry)	Registered	Authorisation granted for one specific application (no CTPHT in final articles)	Yes	No	Yes
Production of carbon and graphite articles	Registered (with service life)	No [1]	No	? [2]	Yes
Production of electrodes for the carbon, graphite, aluminium, calcium carbide, electro-steel, metallurgic smelting industries	Registered (with service life in carbon and graphite industry, electro-steel industry, metallurgic smelting industry)	Authorisations granted for the formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation	No	No	Yes for some electrodes
Rubber and elastomer articles (eg conveyor belts, hand grips)	Not registered	No AfA submitted	No	Yes	Yes
Polyethylene articles (eg synthetic textiles, electrical apparatus)	Not registered	No AfA submitted	No	Yes	Yes
Production of carbon black	Registered (with service life)	Authorisations granted for the formulation of mixtures exclusively for industrial uses	No	No	No

[21] Would include anti-corrosion coatings, road binder/tars, roofing (tar, tar coated glass fiber felts), adhesives in optical equipment.

Table 5: Summary of the uses of CTPHT					
Uses	**Registration status**	**Authorisation status**	**SiA notification**	**SCIP submissions**	**Use in articles**
		that are outside the scope of the authorisation			
Formulation for various industrial uses as intermediate	Registered[22] (one registrant also report a downstream use as biocide outside EEA)	Authorisations granted for the formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation	No	No	No
Production of active carbon	Registered (with service life)	Authorisations granted for the formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation	No	No	No
Fuel (liquid, briquettes)	Registered[23] (with service life for industrial energy production)	No AfA submitted (exempted)	No	No	No
Medicinal/cosmetic applications	Not registered	No AfA submitted	No	No	No

[1] Authorisations were granted for the formulation of mixtures exclusively for industrial uses that are outside the scope of the authorisation. The uses of mixtures for the production of articles is not an intermediate use and is in the scope of authorisation. No application has been received for the production of carbon and graphite articles.

[2] The descriptions of articles in registration dossiers and SCIP database does not enable to acertain without doubt if any of these uses are actually reported in SCIP database.

These assumptions and conclusions have not been contradicted in the call for evidence.

B.2.3 Uses advised against by the registrants

There are no uses advised against in the REACH registrations.

As the sunset date has passed, uses in the scope of authorisation for which no application were submitted, and uses for which authorisations have been refused, must not be registered anymore. Many registrations have not been updated yet.

[22] Under "Use of CTPht for manufacture of formulations for various industrial uses" and/or "Formulation of products from coal tar distillation at production site"

[23] Under "Use of CTPHT as fuel in industrial heavy diesel engines", "Use as a liquid fuel", "use for industrial energy production".

B.2.4 Description of targeting

This report under Article 69(2) is targeted at the risk from uses of CTPHT from articles throughout their lifecycle (including the waste stage), and whether or not such uses should be restricted. Furthermore, targeting is based on the hazard for which the substance was included on Annex XIV, i.e. carcinogenic (Article 57a), Persistent, Bioaccumulative and Toxic (PBT) (Article 57d), and very Persistent and Very Bioaccumulative (vPvB) (Article 57e) properties.

B.3 Classification and labelling

Classification according to CLP

The harmonised classification and labelling of CTPHT is presented in Table 6. Some of the twelve PAHs (listed in Table 1) have a harmonised classification as carcinogen, mutagen or as toxic to reproduction in Annex VI of CLP.

Table 6: Harmonised classification and labelling of CTPHT

Index #	EC #	Classification	Specific Conc. Limits, M-factors	Notes	ATP inserted/updated
648-055-00-5	266-028-2	Muta. 1B (H340) Carc. 1A (H350) Repr. 1B (H360FD)	/	/	CLP00/ATP14

Classification according to the Classification and Labelling Inventory

There have been 6 aggregated notifications to the C&L inventory[24] for CTPHT, most of them reproducing the harmonised classification. In the registration dossiers, the additional endpoints are: Skin Sens. 1, H317, Aquatic Chronic 4; H413; there are 23 notifications Skin Sens. 1, H317 and Aquatic Chronic 4; H413, and 83 notifications of Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

B.4 Environmental fate properties

The evaluation of the fate properties of CTPHT is available in the EU RAR for CTPHT (EU RAR, 2008). It was based on available data for the 12 PAHs considered relevant for the PBT/vPvB assessment of CTPHT. No information on the environmental fate of CTPHT itself was found. According to the Member State Committee support document for identification of CTPHT as a substance of very high concern because of its PBT and CMR properties (ECHA, 2009b), the PBT assessment of CTPHT focused on the assessment of its PAH-constituents having been identified in concentrations above or equal to 0.1 %. For 10 of the 12 PAH-constituents assessed in total, half-lives in soil have been reported to be in the range of 5.7-9.1 years under field conditions. Half-lives observed in soil were reported to exceed the P- and vP-criteria (half lives of 120, respectively 180 days), the vP criterion was fulfilled by all 10 PAH-constituents. Experimentally obtained BCF values >5,000 in fish, mollusks, or crustaceans for nine of the PAH-constituents were reported and exceed the B- and vB criteria (measured BCF values in aquatic species >

[24] Accessed on 23 June 2021

2000 respectively > 5000), it was concluded that the vB-criterion is fulfilled by the respective nine substances. BCF values > 2000 have been reported for anthracene, fulfilling the B-criterion.

The properties of the PBT and vPvB-substances lead to increased uncertainty in the estimation of risk to human health and the environment. This means that, in accordance with section 4 of Annex I of REACH, hazard assessment and exposure estimation cannot be carried out with sufficient reliability[25].

B.5 Human health hazard assessment

In addition to being a PBT and vPvB substance, CTPHT was included in Annex XIV based on its carcinogenic properties (Carc. 1B, later amended as 1A, see B3. Classification and labelling).

CTPHT is considered to be a genotoxic carcinogen. No threshold can be determined below which exposure would be safe. Lung, bladder and skin cancers are identified as the key cancer risk endpoints for exposure to CTPHT, these are the cancers for which data specific to CTPHT exposures exist from animal studies and industrial epidemiology (ECHA, 2018). For the purposes of identifying CTPHT as SVHC for its carcinogenic properties, ECHA (2009b) did not rely on the properties of selected PAHs, and merely referred to the existing harmonised classification of the substance.

Other human health endpoints are not relevant for this dossier. In the context of applications for authorisations, RAC has established a reference dose response relationship for carcinogenicity of CTPHT (RAC, 2018) in which the risk estimates for inhalation, dermal and oral route were derived (Table 7).

Table 7: Overview of reference dose-response relationships for the carcinogenic properties of CTPHT

Route	Cancer type	Lifetime excess risk	
		Workers	General population
Inhalation	Lung cancer	5.6×10^{-6} per ng/m^3 [(a)]	3.0×10^{-5} per ng/m^3
	Bladder cancer	4×10^{-6} per ng/m^3 [(a)]	2.1×10^{-5} per ng/m^3
Dermal	Skin cancer	1.3×10^{-3} per ng BaP/cm^2/day	Not derived [(b)]
Oral	Cancer	Not relevant	2.06×10^{-3} per µg PAH4/kg bw/day 1.43×10^{-3} per µg PAH8/kg bw/day

[a] Exposure levels in air can also be derived from urinary 1-OHP or 3-OHBaP biomonitoring data using the relationships:

- urinary post-shift concentration of 3-OHBaP (µmol/mol creatinine) = 0.001835 x 8h TWA BaP concentration in air (µg/m^3) + 0.1729
- urinary post-shift concentration of 1-OHP (µmol/mol creatinine) = 1.11 x 8h TWA BaP concentration in air (µg/m^3) + 1.13

[25] RAC (2018) notes the following: *In previous risk assessments, e.g. the restriction on decaBDE proposed by ECHA (RAC, 2014), when assessing the risk of PBT and vPvB substances, RAC has taken the view that appropriate information on emissions to the environment can be regarded as a surrogate for risk. The reader is also referred to the RAC opinion on the sole application for authorisation received by ECHA for the substance HBCDD (RAC, 2015).*

[b] No significant exposure of the general population by the dermal route is envisaged. Therefore, no dose-response was derived. However, applicants may use the relationship derived for dermal cancer for workers and convert it to general population as relevant.

In developing its opinions on the application for authorisation, RAC confirmed that it is not possible to determine a DNEL for the carcinogenic (category 1A) properties of the substance in accordance with Annex I of the REACH Regulation.

The properties of the PBT and vPvB-substances lead to increased uncertainty in the estimation of risk to human health and the environment. This means that, in accordance with section 4 of Annex I of REACH, hazard assessment and exposure estimation cannot be carried out with sufficient reliability.

B.6 Human health hazard assessment of physicochemical properties

Not relevant.

B.7 Environmental hazard assessment

Long-term data for marine or freshwater species showing no effect concentrations (NOEC/EC_{10}) < 0.01 mg/l are available for 9 of the PAH constituents present above 0.1 %.

B.8 PBT and vPvB assessment

In addition to its carcinogenic properties, the substance CTPHT was also included in Annex XIV of REACH for its PBT and vPvB properties because seven of the 12 PAH-constituents present in CTPHT in concentrations equal to or above 0.1 % are to be considered as both vPvB and PBT substances and at least 5 to 10 % of its PAH constituents are vPvB and/or PBT[26] (RAC, 2018).

According to RAC (2018), PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long periods of time. The effects of such accumulation are unpredictable in the long-term and practically very difficult to reverse, because a cessation of emissions will not necessarily result in a reduction in chemical concentrations in the environment. The properties of the PBT and vPvB-substances thus lead to increased uncertainty in the estimation of risk to human health and the environment. This means that, in accordance with section 4 of Annex I of REACH, hazard assessment and exposure estimation cannot be carried out with sufficient reliability.

B.9 Exposure assessment

B.9.1 Summary of the existing legal requirements

According to REACH Annex I section 6.5, for substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 [exposure estimation] when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

[26] According to the Agreement of the Member State Committee on Identification of Coal Tar Pitch, High Temperature as a Substance of Very High Concern According to Articles 57 and 59 of Regulation (EC) No 1907/2006, adopted on 2 December 2009 (RAC, 2018).

REACH has several requirements for substances on the candidate list including notification of its presence in articles if the concentration is above 0.1 % and 1 tonne per producer or importer per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1 % by weight of CTPHT (Article 33(b)).

Under REACH, CTPHT was proposed for SVHC listing by ECHA on 1 August 2009, the substance was listed in the candidate list on 13 January 2010 (ED/68/2009) and included into Annex XIV in 2017 (Commission Regulation (EU) No 2017/999). The entries in Annex XIV for CTPHT Authorisation set a latest application date of 4 April 2019 and a sunset date of 4 October 2020 .

CTPHT, as a substance or in a mixture, is restricted with entries 28, 29 and 30 of Annex XVII in REACH (placing on the market for supply to the general public), being placed on the Appendix 1, 4 and 6 respectively.

As regards PAHs, entry 50 of Annex XVII in REACH restricts 8 PAHs (benzo[*a*]anthracene, chrysene, benzo[*a*]pyrene, benzo[*b*]fluoranthene, benzo[*e*]pyrene, benzo[*j*]fluoranthene, benzo[*k*]fluoranthene, dibenzo[*a,h*]anthracene) in specific rubber and plastic articles supplied to the general public. This includes also plastic and rubber coatings onto articles. They are present as impurities in some of the raw materials used in the production of such articles, in particular in extender oils and in carbon black.

Entry 72 of Annex XVII does not prohibit the placing of the market of CTPHT in textiles (although it has a harmonised classification as Carc. 1B), but a number of PAHs contained in CTPHT (Benz[a]anthracene, Benz[e]acephenanthrylene, Benzo[a]pyrene, Benzo[e]pyrene, Benzo[j]fluoranthene, Benzo[k]fluoranthene, Chrysene, Dibenz[a,h]anthracene) are prohibited above 1 mg/kg (0.0001 % w/w).

A proposal for an Annex XV dossier (restriction) of substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in textiles, leather and fur, has been submitted on 12 April 2019 and the final RAC and SEAC opinions were adopted on 17 September 2020. CTPHT does not have a harmonised classification as skin sensitiser. It is self-classified in its registration dossiers as Skin Sens. 1, H317, and should this classification be harmonised, it would fall in the scope of this restriction.

The Occupational Safety and Health (OSH) legislation apply, in particular the Chemical Agents Directive (Directive 98/24/EC)[27], the Carcinogens, Mutagens or Reprotoxic substances at work

[27] Council Directive 98/24/EC of 7 April 1998 on the protection of the health anf safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p11), amended by Directives 2007/30/EC, 2014/27/EU and Regulation (EU) 2019/1243. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01998L0024-20190726

Directive (Directive 2004/37/EC)[28], as well as the Industrial Emissions Directive (IED, Directive 2010/75/EU)[29] and Waste Framework Directive (Directive 2008/98/EC)[30].

Under the Waste Framework Directive, companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1 % weight by weight (w/w) on the EU market have to submit information on these articles to ECHA, as from 5 January 2021.

Several countries have established occupational exposure limits (OELs)[31] for CTPHT (CAS: 65996-93-2) of 0.2 mg/m^3 for 8 hours (Australia, Belgium, Canada, Denmark, France, Japan, New Zealand, China, Singapore, South Korea, Spain, Switzerland, USA) and of 0.14 mg/m3 (Ireland). In addition Denmark has established a short-term limit at 0.4 mg/m^3. There are also 8-hrs OELs for PAHs of 0.2 mg/m^3 (Denmark, Romania), 0.04 mg/m^3 (Norway), 0.002 mg/m^3 (Poland) and short-term value of 0.4 mg/m^3 (Denmark) and PAHs derived from coal (as benzo[a]pyrene) of 0.0005507 mg/m^3 (The Neherlands). A scientific report for evaluation of limit values for PAHs at the workplace has been published by ECHA[32] on 10 May 2022 on request of the European Commission

CTPHT is not an approved biocidal active substance under Regulation (EU) 528/2012.

PAHs are subject to release reduction provisions under the Persistent Organic Pollutants Regulation[33]. The following four indicator compounds shall be used for the purpose of emission inventories: benzo(*a*)pyrene, benzo(*b*) fluoranthene, benzo(*k*)fluoranthene and indeno(1,2,3-*cd*)pyrene. Member States need to have inventories for PAHs released into air, water and land and programmes to reduce, minimise and eliminate releases. Monitoring of PAHs is not mandatory. The PAHs are not listed in the Stockholm Convention.

It is not the purpose of this screening report on CTPHT to list all existing legal requirements related to PAHs. Only the ones that are most relevant to the targeting of the report are mentioned.

Information on existing legislations in European Union relevant for CTPHT is available on ECHA's website under EU Chemicals Legislation Finder (EUCLEF) [34].

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[28] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (OJ L 158, 30.4.2004, p. 50), amended by Directives 2014/27/EU, (EU) 2017/2398, (EU) 2019/130, (EU) 2019/983, Regulation (EU) 2019/1243, Directive (EU) 2022/431. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004L0037-20220405

[29] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0075-20110106

[30] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste (OJ L 312, 22.11.2008, p. 3) amended by Commission Regulation (EU) No 1357/2014, Commission Directive (EU) 2015/1127, Council Regulation (EU) 2017/997and Directive (EU) 2018/851. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705

[31] Gestis International Limit Values database, accessed 12 May 2022.

[32] Available at: https://echa.europa.eu/oels-pc-on-oel-recommendation/-/substance-rev/69728/term

[33] PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).

[34] Available at: https://echa.europa.eu/legislation-finder.

B.9.2 General discussion on releases and exposure

For this report, only releases and exposure from articles summarised in section B.2.2.2 are relevant.

As CTPHT is a PBT and vPvB substance, emissions to the environment can be regarded as a surrogate for risk. No threshold can be derived for the carcinogenic, PBT and vPvB properties. These properties are due to the presence of PAHs in CTPHT. Due to the non-threshold mode of action, the exposures and emissions to human health and the environment must be reduced as low a level as is technically and practically possible[35].The content of PAHs in CTPHT and thus in articles, and the emissions of PAHs from the service life of articles and exposure to PAHs, are underpinning the risks.

PAHs are normally non-reactive and therefore they are not expected to bind covalently to the matrix where they are contained in articles. They can be released from articles during their service life and when articles are disposed of and treated as waste. This leads to releases to the environment and exposure of workers, consumers and general population via the environment.

RAC considered that the use of a selection of PAHs, i.e. indicator PAHs, underestimates the release of constituents with PBT/vPvB and carcinogenic properties of CTPHT and AO to water (ECHA, 2020).

Releases to the environment can be estimated by multiplying the tonnage used in articles with release factors, which represent the fraction of the tonnage in the article released to the environment during their service life (indoor/outdoor/at industrial site) and the waste stage (shredding/landfilling/incineration). In absence of specific information, it is assumed that the generic release factors of ECHA guidance R16 (ECHA, 2016) and R18 (ECHA, 2012) apply. These release factors are displayed in Table 8.

[35] Note on reference dose-response relationship for the carcinogenicity of pitch, coal tar, high temperature and on PBT and vPvB properties.
https://echa.europa.eu/documents/10162/17229/ctpht_rac_note_en.pdf/a184ee42-0642-7454-2d18-63324688e13d?t=1544526560573

Table 8: Default release factors to the environment for articles service life and disposal (ECHA, 2012, 2016)			
Environmental release scenario / category	Default worst-case release factors		
	To air	To water (before STP)	To soil
Widespread use of articles with low release (outdoor) (ERC 10a)	0.05%	3.2%	3.2%
Widespread use of articles with high or intended release (outdoor) (ERC 10b)	100%	100%	100%
Widespread use of articles with low release (indoor) (ERC 11a)	0.05%	0.05%	n.a.
Widespread use of articles with high or intended release (indoor) (ERC 11b)	100%	100%	n.a.
Processing of articles at industrial with low release (ERC 12a)	2.5%	2.5%	2.5%
Processing of articles at industrial site with high release (ERC 12b)	20%	20%	20%
Use of articles at industrial sites with low release (ERC 12c)	0.05%	0.05%	n.a.
Shredding of waste	10%	0	0
Landfilling waste	0	1.6%	1.6%
Incineration of waste	0.01%	0.01%	0

Human exposure is assessed qualitatively since information is lacking on the articles to perform a quantitative assessment. No threshold can be determined below which exposure would be safe. Exposure via inhalation to volatile components (e.g. PAHs emitted especially during use at high temperature) and to dust (in case of grinding, sawing etc of articles), as well as dermal exposure to PAHs in the surface of articles of from dust, can be expected. Oral exposure from articles may occur in case e.g. small children are mouthing the articles. Nevertheless, as there are already restrictions prohibiting use of PAHs in toys and other articles which they can place in the mouth (entry 50 of Annex XVII), oral exposure route is considered negligible.

Use in clay targets

The use of CTPHT in clay targets presents an EU-wide risk to human health and the environment due to the release to the environment of several hundred tonnes of PAHs per year (ECHA, 2020). Several alternatives to CTPHT are currently in the market. Although most of the alternatives contain PAHs at concentrations lower than that of CTPHT, alternatives containing PAHs also present a risk to the environment and human health.

In order to ensure a high protection of human health and the environment in the EU and avoid regrettable substitution, the Commission has requested ECHA to prepare an Annex XV restriction dossier on substances containing PAHs in clay targets for shooting, incorporating the Article 69(2) assessment for CTPHT.

ECHA submitted an Annex XV restriction dossier on 1 October 2021. The proposal is based on a concentration limit of indicator PAHs in the clay targets. RAC and SEAC have adopted their opinions on 13 September 2022 and 2 December 2022 respectively[36].

Use in paints, coatings, sealants, adhesives and waterproofing materials which may become integral parts of articles

Overall, little information is available on the nature of the articles where these types of incorporation occurs outside the EU, on the likelihood that these articles are imported to the EU and which tonnage that would represent, and on releases of CTPHT and PAHs from articles.

The amount of CTPHT that could be imported via these articles is unknown. Current tonnage information in registrations for this use cannot be relied upon, as they have not been updated after the sunset date. Because no authorisation were sought for these uses, registrations must be updated to reflect that this use in paints, coatings, sealants, adhesives and waterproofing materials is not allowed in the EU anymore and thus only the imported tonnage would remain.

Taking into account the non-threshold carcinogenic hazard and PBT/vPvB properties of the substance, it is reasonable to assume that human exposure from the handling of such articles, as well as releases to the environment during service life and waste stage would pose a risk for human health and the environment.

ECHA considers that the service life of these articles would lead to low releases indoor, outdoor and to the environment, as well as from handling of the articles as waste. Taking into account the default factors of Table 8, for each 100 tonnes incorporated in articles:

- the processing of articles at industrial site would lead to releases of 7.5 tonnes (ERC 12a)
- the service life outdoor would lead to releases of 6.45 tonnes (ERC 10a)
- the service life outdoor would lead to releases of 0.1 tonnes (ERC 11a)
- the shredding of articles disposed of as waste would lead to releases of 10 tonnes
- the landfilling of articles disposed of as waste would lead to releases of 3.2 tonnes
- the incineration of articles disposed of as waste would lead to releases of 0.02 tonnes.

Under these assumptions, the total release to the environment from the service life and waste stage would be up to 27.3 tonnes per 100 tonnes incorporated in articles.

It is possible that e.g. painted or coated articles are ground, drilled, sawed etc which can generate dust and inhalation exposure from this kind of activities cannot be excluded.

Information in SCIP database suggest that some articles can be imported (e.g. articles containing adhesives). No information has been submitted in the call for evidence to confirm or contradict that such articles are imported, neither to support a more specific release and exposure estimation.

[36] Available at: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e186716202.

Uses in refractory applications, some carbon electrodes and in other carbon and graphite articles

Refractory articles are mainly used within industrial settings, so most probable exposure concerns workers and environment in the waste stage.

CTPHT can be used to produce refractory articles as a binder or by impregnation. There are many possibilities in terms of materials and processes used to obtain a final refractory article. When CTPHT is used as a binder, it is added to other materials (e.g. carbon-based filling) to hold the various pieces and keep the particles together. The mix (named paste) is shaped and then baked. The product obtained can also be subsequently impregnated with CTPHT and baked again several times for further reinforcement of the final product. According to information from the SiA notification and information provided by the refractory sector[37], CTPHT is also used to produce functional articles such as sliding gates. In this case a "raw body" (a microporous refractory item made of e.g. aluminium oxide) is first impregnated with CTPHT and is subsequently fired. During the production process, CTPHT is transformed into pitch coke (CAS 140203-12-9). After firing, the functional article is further machined to a certain shape (e.g. by grinding, cutting etc.) and assembled. Bricks would not be machined but would be used as such.

The production of electrodes and carbon articles entails similar production steps and only the shape and further use would differ.

Because these uses have all been considered intermediate uses by industry without distinguishing whether substance or article is produced from these uses, it is not possible to use registration to assess the potential for exposure to CTPHT/PAHs during the subsequent service life of the articles. However, as described in section B.2.2.2 Conclusions: uses in articles to be considered in this report in accordance with Article 69(2), shaped refractory articles and functional articles made of refractory material, as well as carbon and graphite articles and some types of electrodes, are not intermediate uses, and service life of these articles, which may lead to workers exposure and to releases to the environment, has to be considered. Because the production of articles is in the scope of authorisation, the production of articles other than the ones specifically identified in the granted authorisation (REACH/21/1/0)[38] is not allowed anymore in the EU. However, as industry consider that these uses are out of scope of authorisation (i.e. intermediate use, as explained in B.2.2.2), illegal production of such articles in the EU may still exist and has to be dealt with via enforcement. Consequenlty, the considerations given below regarding potential exposure to CTPHT/PAHs in articles apply to imported articles.

First, it needs to be determined whether CTPHT or PAHs as markers of CTPHT are present in the imported articles. The manufacturing process of these articles entails firing at elevated temperature and CTPHT is intended to be transformed into pitch coke (CAS 140203-12-9) or graphite. According to information received from the industry in the context of ECHA's 6th Recommendation for the inclusion of substances in Annex XIV (ECHA, 2015a), the use of CTPHT in impregnating shaped refractory products should not result in CTPHT in the finished article, as the firing step in the production process is claimed to transform all CTPHT applied to the item surface to pitch coke (ANFRE, 2016). Based on available information in SiA notification, however,

[37] National Association of Manufacturers of Refractories, Materials and Related Services (ANFRE). ANFRE presented the view of the European Refractories Producers Federation (PRE) that the use of CTPHT in sliding gates is an intermediate http://www.anfre.com/coal-tar-pitch-high-temperature-ctpht-in-the-refractory-industry-intermediate-under-reach-art-3-15/

[38] No risk from the service life of articles was identified in this application for authorisation.

it could be assumed that some residual CTPHT may still remain in articles as impurities in pitch coke. Pitch coke is exempted from registration[39] (Annex V of REACH) and the identity and concentration of impurities is not known. The German Environment Agency (UBA, 2022) investigated the possible transfer of constituents of concern such as PAHs during carbonisation and graphitisation of CTPHT and noted that some PAHs may be transferred and thus be present in the resulting articles. Although exposure of workers and releases to the environment of PAHs during production of coke and refractory material is a well-known issue (Bieniek, 2012; Sartorelli, 2020; Tamang, 2022; ECHA, 2009a; ECHA, 2022), no specific publication was found related to the content of PAHs in articles resulting from these processes[40].

Second, it should be assessed if CTPHT/PAHs can be released and lead to human exposure and releases to the environment during the service life of imported articles and when they become waste. However, the amount as well as the availability of CTPHT/PAHs from the matrix are uncertain and it is not possible to perform a quantitative estimation. Qualitatively, as CTPHT is used both inside and on the surface of articles, it is assumed that any residual CTPHT/PAHs will be available for dermal exposure when processing the articles (machining, assembling), during their use e.g. as furnace lining or as sliding gate, and while handling articles at their end of life (waste stage, recycling (Horckmans, 2019; Refrasort project[41]). Upon use, these articles will be subject to high temperatures but it is uncertain if CTPHT/PAHs may be emitted to air and if risk management measures in place are sufficient to capture the emitted substances. Regarding releases to the environment, in absence of specific data, releases could be quantified based on tonnage and release factors using the default release factors presented in Table 8 (i.e. ERC 12a, 12b, 12c, as well as for the waste stage). However no information is available on the tonnage of imported refractory articles, carbon electrodes, other carbon and graphite articles made with CTPHT to enable any quantification.

It should be noted that the releases and exposure minimisation obligation under REACH and provisions of the occupational safety and health (OSH) legislation as well as industrial emissions directive (IED) have to be followed; risk management measures have to be implemented to minimise exposure and emissions accordingly. OELs are established as presented in section B.9.1 above. For waste, although it can be assumed that these articles will be handled as hazardous waste, this cannot be certain. The European List of Waste[42] defined in the Waste Framework Directive (WFD) includes waste linings and refractories under codes 16 11 (mirror entries requiring an assessment to determine whether the waste is hazardous based on the content of hazardous substances).

In conclusion, releases to the environment and exposure of workers and of general population via the environment to CTPHT or PAHs from the uses of imported articles cannot be excluded. The existing legislatives measures under REACH (obligation to minimise releases and enforcement of authorisation), OSH, IED and WFD should in principle ensure some level of minimisation of occupational exposure and releases to environment from industrial processes

[39] Entry 10 of the Guidance for Annex V, ECHA, 2012: https://echa.europa.eu/documents/10162/23036412/annex_v_en.pdf/8db56598-f7b7-41ba-91df-c55f9f626545.

[40] Search performed on 3 June 2022 on Web Of Science with the keywords: polycyclic aromatic hydrocarbon coke refractory.

[41] https://cordis.europa.eu/article/id/197342-how-to-turn-refractory-waste-back-into-raw-materials

[42] COMMISSION DECISION of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0955&from=EN

and waste, however the effectiveness of these existing regulatory instruments is not known. Therefore, occupational exposure and releases from the industrial uses of these articles and waste cannot be excluded. No further information has been received in the call for evidence to allow a quantitative assessment.

Use in rubber and elastomer articles

Little information is available to assess the exposure from these uses. As there is no SiA notification under Article 7(2) of REACH, the amount placed on the market is likely below 1 tonne per importer per year (however, if there would be lots of importers, the total tonnage could be much higher). The service life of conveyor belts can lead to emission of particles due to friction. Dermal exposure due to contact with hand grips of golf equipment or hand tools can be of concern as well. Regarding releases to the environment, a generic estimation can be made using the defaults release factors listed in Table 8. The tonnage of substances in these articles is however not known.

It is to be noted that restriction entry 50 on certain PAHs restricts the amount of PAHs in these articles, when supplied to the general public. Assuming that these articles contain a minimum concentration of 0.1 % of CTPHT (which is the threshold triggering a notification) and that CTPHT contains PAHs at the concentration indicated in Table 1 (section B.1.2), some PAHs would be expected to be present in these articles above the limit set in the restriction entry 50. This identified risk has to be addressed by enforcement. It should also be noted that entry 50 only targets risks due to carcinogenicity, but not due to PBT/vPvB properties, and therefore even if entry 50 were properly implemented, there could be an uncontrolled risk to the environment, if articles listed above and placed on the market in compliance with entry 50 contain other PBT and/or vPvB PAHs.

Since the call for evidence did not produce any new information concerning the use of CTPHT in articles, the assumptions are still valid.

Use in polyethylene articles (eg synthetic textiles, electrical apparatus)

Little information is available to assess the exposure from these uses. As there is no SiA notification under Article 7(2) of REACH, the amount placed on the market is likely below 1 tonne per importer per year (however, if there would be lots of importeds, the total tonnage could be much higher). The SCIP submissions report uses in synthetic textiles (e.g. bags, tents) which can lead to dermal and inhalation exposure, as well as release to the environment (for instance for outdoor tents subject to rain). Regarding releases to the environment, a generic estimation can be made using the defaults release factors listed in Table 8. The tonnage of substances in these articles is however not known. For electrical devices, this would depend on how the substance is incorporated and if the parts are accessible or not; but in any case they will become waste (WEEE). Recycling may be of concern, however this cannot be assessed.

It should be noted that restriction entry 72 restricts the amount of some PAHs in textiles (taking into account the same reasoning than above for rubber and elastomer articles, as the concentration limit that applies for PAHs is identical), leading here as well to an identified risk that has to be addressed by enforcement. Risks due to PBT and/or vPvB properties of the PAHs are not addressed by entry 72.

Since the call for evidence did not produce any new information concerning the use of CTPHT in articles, the assumptions are still valid.

B.10 Risk characterisation

Since CTPHT is a vPvB and PBT-substance, RAC did not previously support a quantitative risk assessment in its assessment of the submitted applications for authorisation. RAC considered that emissions of CTPHT are a suitable proxy for assessing risks to the environment and to humans exposed via the environment (ECHA 2020). PAHs underpin the risks of CTPHT and therefore emissions of PAHs are a suitable proxy for assessing risks to the environment and to humans exposed via the environment to CTPHT. This is consistent with previous restrictions on PBT and vPvB substances, including with the proposal to restrict substances containing PAHs in clay targets for shooting that stems from the risks identified for CTPHT, and that include imported articles and other PAH-containing alternatives to CTPHT.

CTPHT as well as many PAHs are considered genotoxic carcinogens. No threshold can be determined below which exposure would be safe. The reference dose response relationship established by RAC for carcinogenicity of CTPHT (RAC, 2018) for inhalation, dermal and oral route, has to be considered (Table 7).

As no safe threshold limit can be established, it is considered that any presence of CTPHT and PAHs due to the use of CTPHT, in articles made of polymers (e.g. rubber, elastomer, polyethylene) and/or incorporating paints, coatings, sealants, adhesives and waterproofing materials, not already regulated under restrictions (e.g entries 50, 72), authorisation and other legislations, potentially poses a risk during the service life of the articles and/or their disposal as waste.

Risks to human health and the environment due to PAHs in articles are not limited to articles made with CTPHT, but are also relevant for articles made with other PAH-containing substances.

According the Annex I paragraph 6.5, ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012) and the 'Common approach of RAC and SEAC in opinion development on applications for authorisation'[43], the adequate control route is not possible for a non-threshold substance (such as CTPHT[44]). Similarly, when a substance is present in articles, the releases of the substance from articles / exposure of the substance when present in articles need to be as low as technically and practically possible.

[43] https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf

[44] In practice, this means that applicants for authorisation have to demonstrate the rationale for an authorisation via the so-called socio-economic route. RAC will analyse if operational conditions and risk management measures ensure that the exposure levels are as low as technically and practically possible, however.

C. Available information on alternatives

Information retrieved from ECHA (2009a) is presented below.

Refractories: the technical suitability of the binder depends on the intended use of the refractory article, for example: heat and abrasion resistance in the production of iron in a blast furnace; mechanical strength and heat resistance in hot spots in electric arc furnace, non-wetting properties to molten aluminium in aluminium production.

Known alternatives include:

- phenolic resins; the European Phenolic Resin Association website provides information on various refractory applications in which phenolic resins may be used, including manufacture of carbon bonded brick, manufacture of iso-pressed products, tap hole clay resins and monolithic applications (EPRA, 2021)

- petroleum pitches or pitches obtained from a special high temperature vacuum treatment of coal tar pitch. These substances also contain PAHs and are thus unsuitable alternatives.

Paints, coatings, roofing: information received from 4 companies during the Annex XV report development (ECHA, 2009a) reveal that coal tar free alternatives are available, for instance pure epoxy or modified epoxy products, phenalkamines (Cardolite) and technology based on polyamide, polyurethane or acrylic (Cardolite) in ship building. In roofing, there are available alternatives (EPDM membrane, thermoplastic polyolefin, modified bitumen roofing, liquid-applied monolithic roof system, built-up asphalt roofs and metal sheeting).

Clay targets: alternatives to CTPHT in clay targets are addressed in a separate Annex XV report[10].

No further information has been received in the call for evidence.

D. Justification for action on a Community-wide basis

As no safe threshold limit can be established, it is considered that any presence of CTPHT and PAHs due to the use of CTPHT, in articles made of polymers (e.g. rubber, elastomer, polyethylene) and/or incorporating paints, coatings, sealants, adhesives and waterproofing materials, not already regulated under authorisation and other legislations, potentially poses a risk during the service life of the articles and/or their disposal as waste, and should be further investigated.

ECHA is of the view that further examination of the risks from the presence of PAHs from the use of CTPHT in articles should be considered as part of a larger investigation to address risks of PAHs in articles, including from other sources than CTPHT, with concerns to human health and the environment (carcinogenicity, PBT, vPvB). This cannot be addressed under Article 69(2) but requires another legal basis, e.g. under Articles 69(1) or 69(4). ECHA considers that a restriction under Article 68(2) of REACH would not address the risks related to PBT/vPvB properties of CTPHT/PAHs as Article 68(2) covers only carcinogenic, mutagenic and reprotoxic properties.

The reasons are given below:

Annex XV, paragraph II.3, requires that a restriction shall be assessed using the following criteria: effectiveness, practicality and monitorability.

Effectiveness

A restriction shall be targeted to the effects or exposures that cause the risks identified. PAHs are hazardous constituents in CTPHT which may be at the origin of risks from its use in articles and therefore, ECHA considers that a restriction should target the presence of PAHs in articles to fulfil this criterion.

Other articles, not made using CTPHT, can also contain PAHs and would also lead to similar concern if exposure and/or releases occur. Carry-over of PAHs can also occur during intermediate uses of substances (UBA, 2022). ECHA considers that it is more efficient and effective to investigate risks of PAHs in articles from all substances/sources, on the basis of non-threshold carcinogenic, PBT and vPvB properties of PAHs, and propose additional measures, if the existing measures would be concluded not sufficient. This would also ensure that regrettable substitution to other PAH-containing substances is avoided.

A restriction must be capable of reducing the risks to an acceptable level within a reasonable period of time and proportional to the risk. This has been done in previous restrictions on PAHs in articles (entry 50; proposal for restriction of substances containing PAHs in articles) by establishing concentration limits in articles (in practice, a limit to the sum of the concentration of selected indicators PAHs in articles).

Practicality

Article 69(2) is targeted to presence of Annex XIV substances in articles. As the production of articles with CTPHT in the EU is now completely banned, as the sunset date is passed, and unless an authorisation has been granted[45], only imported articles remain of concern (as well as any

[45] For CTPHT, only one authorisation was granted which lead to the production of articles (REACH/21/1/0). See section B.2.2.

articles placed on the EU market before the sunset date and – for clay targets – before 16 March 2022, date when authorisations have been refused).

From an enforcement point of view, it is not possible to measure 'CTPHT' in a finished articles because it is a UVCB substance and enforcement can only be achieved by measuring the constituents in articles, i.e. PAHs. For this reason, any regulatory action (e.g. restriction) has to target PAHs in articles rather than CTPHT in articles.

Monitorability

The monitoring of the result of the implementation of a restriction on CTPHT/PAHs in articles (especially imported articles) can rely on analytical methods and measurement of the presence and concentration of PAHs in articles. It should be noted that measuring the presence and concentration of PAHs in articles cannot distinguish PAHs coming from a use of CTPHT, against PAHs from other substances/sources. Therefore, targeting PAHs in articles would not allow reliable monitoring of the effectiveness on release/exposure minimisation of CTPHT only. Therefore a restriction of CTPHT under Article 69(2) is considered not monitorable. For this reason, it is proposed that the risks from the presence of PAHs from the use of CTPHT in articles should be considered as part of a larger investigation to address risks of PAHs in articles from all sources and not only CTPHT.

In summary, ECHA concludes that, if a risk is not adequately controlled, the following Community-wide actions could be envisaged:

- Option 1: restriction on CTPHT in articles; however for the reasons stated above this would not be effective, practical/enforceable nor monitorable.

- Option 2: restriction on PAHs in articles; a restriction targeting the constituents of concern (i.e. PAHs) would be more effective, practical/enforceable and monitorable, than a restriction targeting the substances that contain them (option 1). This option is the preferred option. This investigation should identify relevant PAHs as well as relevant articles, beyond the articles listed in this screening report, which is limited to CTPHT but does not include other articles containing PAHs from incorportation of other substances into/onto articles.

ECHA also notes that there are uses of CTPHT in the EU which are in the scope of authorisation but for which no applications have been submitted, as industry consider them out of scope of the authorisations. The incorporation of CTPHT into articles in the EU cannot be subjected to new restrictions according to Article 58(5). It is in the remits of National Enforcement Authorities to ensure that REACH obligations regarding authorisation of uses of CTPHT in the EU are respected.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

Not relevant, as no restriction is proposed at present.

F. Socio-economic Assessment of Proposed Restriction

Not relevant, as no restriction is proposed at present.

G. Stakeholder consultation

The call for evidence, which took place between 17 September 2021 and 29 October 2021, did not identify any new uses of the substances in articles placed on the EU market.

Stakeholders where invited to provide information on:

- uses in articles (any missing uses);
- electrodes used in other sectors than the aluminium industry (how they are used, and, if carbon-based, whether the carbon contained in those electrodes has a specific chemical function in the metal production process);
- use of CTPHT in metallurgical smelting industry and electro-steel industry;
- further details on articles and their uses (shape, size, material(s), users (consumers, professional workers, industrial workers), place of use (indoor, outdoor, enclosed, etc), what it is used for, conditions of use, tonnage, concentration of CTPHT/PAHs in articles, releases and exposure from the use, analytical methods, alternatives).

One comment has been received from a Member State Competent Authority. The comment identified a study (Hebisch *et al*., 2020) which measured inhalation and dermal exposure of workers to PAHs during impregnation of wood with creosote tar oils. This is however not an identified use of CTPHT in articles. Methodological work for the analysis of dermal exposure to hazardous chemical agents at the work-place (SysDEA project) was also brought to the attention of ECHA (Kasiotis *et al*., 2020). Two ongoing research projects on "Intermediate Uses of PetCo Substances" and "Development of a chemical analysis concept for substances derived from coal and petroleum stream"[46] where also mentioned. The first one is not published yet but ECHA had access to preliminary results.

No specific information in response to the questions listed above have been received in the call for evidence.

This final report takes into account the information received on CTPHT during the call for evidence.

[46] Available at: https://www.umweltbundesamt.de/en/publikationen/development-of-a-chemical-analysis-concept-for

H. Other information

Not relevant.

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Annex 1

Composition of CTPHT (EU RAR, 2008, cited in ECHA, 2009b)

Chemical name	EC number	CAS number	Concentration in impregnating pitch (%)	Concentration in binder pitch (%)
Naphthalene	202-049-5	91-20-3	n.d.	n.d.
Acenaphthylene	205-917-1	208-96-8	n.d.	n.d.
Acenaphthene	201-469-6	83-32-9	0.039	0.043
Fluorene	201-695-5	86-73-7	0.014	0.047
Phenanthrene	201-581-5	85-01-8	0.387	0.630
Anthracene	204-371-1	120-12-7	0.074	0.131
Fluoranthene	205-912-4	206-44-0	1.739	1.079
Pyrene	204-927-3	129-00-0	1.485	0.945
Benz(a)anthracene	200-280-6	56-55-3	1.501	0.772
Chrysene	205-923-4	218-01-9	1.404	0.805
Benzo(b)fluoranthene	205-911-9	205-99-2	1.741	1.213
Benzo(k)fluoranthene	205-916-6	207-08-9	0.870	0.607
Benzo(a)pyrene	200-028-5	50-32-8	1.292	1.002
Dibenzo(a,h)anthracene	200-181-8	53-70-3	0.221	0.175
Benzo(ghi)perylene	205-883-8	191-24-2	0.995	0.866
Indeno(1,2,3cd)pyrene	205-893-2	193-39-5	1.111	0.906

n.d. = not detected (detection limit 50 mg/kg)

Annex 2

Database searches (10 May 2021)	URL
Danish Chemicals in Consumer Products Database	https://vidensbank.mst.dk/v2/
Consumer Product Information Database CPID (USA & Canada)	https://www.whatsinproducts.com/
US EPA Comptox (includes: CDR[47], SIRI[48]) (searched on 1 June 2021)	https://comptox.epa.gov/dashboard
OECD Global Products Recall	https://globalrecalls.oecd.org/#/
Children's Safe Product Act Reported Data	https://hpcds.theic2.org/Search
RAPEX notifications database (EU Safety Gate)	https://ec.europa.eu/safety-gate-alerts/screen/search
Substances in preparations in Nordic countries (SPIN database)	http://www.spin2000.net
KEMI Commodity guide.	http://webapps.kemi.se/varuguiden/Default.aspx

Keywords used: 266-028-2, 65996-93-2, "Pitch, coal tar, high temperature", CTPHT

Searches were performed in Google Scholar for the last ten years, to identify further uses of the substances in articles. Keywords used: 266-028-2 (N=11), 65996-93-2 (N=60), "Pitch, coal tar, high temperature" (N=10), CTPHT (N=38).

[47] Chemical Data Reporting (2014) (CDR) data submitted to US-EPA under the Toxic Substances Control Act (TSCA).

[48] Compilation of MSDS extracted on 27 February 2019. The database may no longer be maintained.