

ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF ANTHRACENE OIL IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: Anthracene oil

IUPAC Name: Anthracene oil

EC NUMBER: 292-602-7

CAS NUMBER: 90640-80-5

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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 REACH¹ and the Waste Framework Directive (SCIP database²)) 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 REACH³. 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 types of uses⁴:

- 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 becomes an integral part of the composition of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements⁵, while only few exemptions are envisaged in case of restrictions. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to

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

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

Anthracene oil (AO) has been included on the Candidate List (13/01/2010; 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 category 1B (Article 57a)⁶, Persistent, Bioaccumulative and Toxic (PBT) (Article 57d), and very Persistent and Very Bioaccumulative (vPvB) (Article 57e) properties (specific constituent PAHs) were considered relevant to establish the PBT/vPvB properties of AO).

ECHA has gathered information on the uses of anthracene oil 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 AO in articles placed on the EU market. Additional publications and upcoming publications were brought to the attention of ECHA. In parallel, ECHA conducted a dossier 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 AO to update their registration dossiers. This version of the report takes into account the 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 AO in articles leading to a presence of PAHs that have the potential to lead to environmental releases / human exposure (cf sections B.2 and B.9). The identified uses of AO in articles are summarised in section A.3.1 and described in detail in section B.2.

Based on this screening work, 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 PAHs in articles 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^{Error! Bookmark not defined.}.

ECHA also notes that there are uses of AO 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

⁶ Does not meet the criteria for identification as a carcinogen if it contains < 0,005 % (w/w) benzo[a]pyrene (Einecs No 200-028-5).

National Enforcement Authorities to ensure that REACH obligations regarding authorisation of uses of AO in the EU are respected.

A.2 Targeting

This report under Article 69(2) is targeted at the (uncontrolled) risks from uses of AO in articles throughout their lifecycle (including the waste stage) and whether or not such use should be restricted. The report is focused on both environmental and human health 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), four applications for authorisation had been submitted to ECHA (Applications for authorisation ECHA (2020)), requesting similar authorisation for: Use of anthracene oil for manufacture of formulations for various (intermediate or biocidal) industrial uses. All the uses applied for are conducted at industrial sites in closed systems and include manufacture of carbon black, creosote (biocidal product) and export. The applications did not include any incorporation of the substance in articles in their assessments. All the applications were granted authorisation.

As of 22 June 2022, anthracene oil is registered at more than 100 000 tonnes per annum. Registered uses relevant for this screening report in the nine active registrations are: production of refractory articles and widespread uses by professionals of paints, coatings, adhesives, sealants and waterproofing materials containing anthracene oil with possible incorporation into/onto articles.

At the time of this screening report, ECHA did not receive any substance in article notifications under Article 7(2) of REACH (SiA notifications) concerning anthracene oil.

Public database searches and uses submitted to ECHA under Article 9(1)(i) of the Waste Framework Directive (so-called SCIP Submissions) confirmed the above-mentioned uses but also suggested other use categories in which anthracene oil may be incorporated into articles. This incorporation is assumed to occur outside EU/EEA, and thus imports of articles containing the substance is possible.

To conclude, based on this screening exercise, article types that contain or may contain anthracene oil are the following:

- articles onto which paints, coatings, sealants, adhesives, binding agents and waterproofing materials are applied (e.g. machinery, equipment, vehicles, other transport equipment),
- refractory products
- articles in which lubricants, greases, and oils products are used (motor vehicles/heavy machinery, parts and accessories of mechanical machinery),
- articles where co-polymers and polymers of ABS (thermoplastic) and other rubber are used,
- articles for construction made from cement or stone,
- articles of wood.

These screened uses are in line with information gathered during the SVHC listing and recommendation for the inclusion of anthracene oil in Annex XIV (ECHA 2008).

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

Anthracene oil 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 (2009) concluded that anthracene oil fulfils the PBT and vPvB criteria as some of its constituents fulfil the PBT/vPvB criteria. In particular, it contains 3-25 % anthracene which has been placed on the Candidate List due to the identification as a PBT substance. It also contains 10-35 % phenanthrene, 2-15 % fluoranthene and 1-10 % pyrene, which all fulfil the vPvB criteria; in addition, fluoranthene and pyrene fulfil the PBT criteria.

In addition, according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008, the classification as carcinogen (Carc. 1B, H350) must be applied to anthracene oil unless it can be shown that the substance contains less than 0.005 % w/w benzo[a]pyrene (EINECS No 200-028-5).

Information on emissions/release/exposure

The hazardous properties of AO originate from its constituent PAHs. Therefore, the content of PAHs in AO 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, acrylonitrile butadiene styrene), cement, stone or wood, dyed textile, leather and fur articles and/or articles incorporating AO-based paints, coatings, sealants, adhesives, waterproofing materials and lubricants, greases, and oils products are used.

Characterisation of risk

As no safe threshold limit can be established, it is considered that any presence of AO (and PAHs due to the use of AO), in articles made of polymers (e.g. rubber, acrylonitrile butadiene styrene), cement, stone or wood, dyed textile, leather and fur articles and/or articles incorporating AO-based paints, coatings, sealants, adhesives, waterproofing materials and lubricants, greases, and oils, potentially poses a risk during the service life of the articles and/or their disposal as waste.

Considering risks to human health and the environment due to PAHs in articles, they are not limited only to articles made with AO, 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 AO and PAHs due to the use of AO 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 AO 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). This 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 AO 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). The incorporation of AO 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 AO 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:	Anthracene oil
EC Number:	292-602-7
CAS Number:	90640-80-5
IUPAC Name(s):	Anthracene oil

B.1.2 Composition of the substance(s)

Chemical name:	Anthracene oil
EC number:	292-602-7
CAS number:	90640-80-5
IUPAC name(s):	Anthracene oil
Molecular formula:	Not applicable
Structural formula:	Not applicable
Molecular weight:	Not applicable
Typical proportion %:	Not applicable
Concentration range %:	Not applicable

Anthracene oil is a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials) consisting of three- to five-membered condensed aromatic hydrocarbons. Depending on the composition, it is a solid or an oily liquid with a colour ranging from yellow over dark green to brown and it is produced during the distillation of coal tars. Coal tars are the condensation products obtained by cooling of the gas evolved in the carbonization process of coal. The relative proportions of the constituents of anthracene oil are complex and variable and dependent on whether low temperature or high temperature processes were involved in the production of the tar. Over 400 constituents have been identified in coal tars, and probably as many as 10,000 are actually present (International Agency for Research on Cancer (IARC), 1985). The number of constituents present in most anthracene oils is estimated in the hundreds. According to the EC inventory anthracene oil is a complex combination of polycyclic aromatic hydrocarbons (PAHs) obtained from coal tar having an approximate distillation range of 300°C to 400°C. It is composed primarily of phenanthrene, anthracene and carbazole.

Table 1: Generic constituents and their compositions (ECHA, 2009)

Constituent	EC no.	CAS no.	Molecular formula	Molecular weight	Content range (% w/w)
Phenanthrene	201-581-5	85-01-8	C ₁₄ H ₁₀	178.23	10 - 35
Fluoranthene	204-927-3	129-00-0	C ₁₆ H ₁₀	202.26	2 - 15
Pyrene	204-927-3	129-00-0	C ₁₆ H ₁₀	202.26	1 - 10
Fluorene	201-695-5	86-73-7	C ₁₃ H ₁₀	166.22	1 - 16
Anthracene	204-371-1	120-12-7	C ₁₄ H ₁₀	178.23	3 - 25
Carbazole	201-696-0	86-74-8	C ₁₂ H ₉ N	167.21	1 - 10
Benzo(a)pyrene (BaP)	200-028-5	50-32-8	C ₂₀ H ₁₂	252.32	< 0.05
Acenaphthene	201-469-6	83-32-9	C ₁₂ H ₁₀	154.21	0.2 - 16
Dibenzofuran	205-071-3	132-64-9	C ₁₂ H ₈ O	168.19	0.1-8

B.1.3 Physicochemical properties

Table 2: Summary of physico-chemical properties of anthracene oil (ECHA, 2009)

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20°C and 101.3 kPa	solid, liquid
VII, 7.2	Melting/freezing point	< 80 °C
VII, 7.3	Boiling point	> 270 °C
VII, 7.5	Vapour pressure	< 1 hPa at 20°C
VII, 7.7	Water solubility	0.041 – 1,98 mg/l
VII, 7.8	Partition coefficient noctanol/water (log value)	3.84 – 5.20

B.1.4 Justification for grouping

ECHA proposes that further examination of the risks from the presence of PAHs from the use of AO 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 AO, but are also relevant for articles made with other PAH-containing substances. In particular, Coal tar pitch, high temperature (EC 266-028-2) 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 consider also other PAH-containing substances besides AO and CTPHT.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

Anthracene oil is an oily liquid produced during the distillation of coal tars at 300°C to 400°C. It is composed primarily of phenanthrene, anthracene and carbazole.

According to active registrations on 22 June 2022, more than 100 000 tonnes of anthracene oil is manufactured/imported annually in the EU. Previously, a total annual volume of 195 000 t/y was reported (ECHA, 2015) from which 56 % goes to the production of carbon black feedstock and 3 % can result in inclusion into articles. Before that, the main use of anthracene oil was reported as intermediate in the production of pure anthracene, which is intensively used in the production of dyes (Germany, 2009). Based on the applications for authorisations, the tonnage for uses in the scope of authorisation is more than 26 000 t/y on four independent sites, one site for each Application for authorisation. While notifications indicate that in 2021, 19 232 tonnes of anthracene oil is exported from the EU⁷, the amount of export or global market is uncertain.

Manufacturing and import of a substance may continue today for authorised uses, uses exempted from authorisation or for export.

B.2.2 Uses in articles

B.2.2.1 Information on uses

Applications for authorisation

Since the sunset date, ECHA received four applications for authorisation for anthracene oil for which which were all granted March 2022 (Applications for authorisation ECHA (2020)), see Table 3. These applications concern the use of anthracene oil in formulation of mixtures. Downstream uses of formulations are claimed to be intermediate uses, and are thus not relevant in relation to the inclusion of anthracene oil into articles.

⁷ ECHA website, Chemicals subject to PIC, Export notifications

Table 3. Information on Applications for Authorisation of anthracene oil⁸

Use applied for by the applicants	Tonnage (t/y)	Emissions to the environment per year	Status of the authorisation and Remarks	ID
Use of anthracene oil for manufacture of formulations for various industrial uses <i>(carbon black feedstock and creosote)</i>	5 000 - 50 000	6.17 × 10 ⁻³ kg (9 PAHs)*	Authorisation partially granted (REACH/22/11/1) on 16/03/2022	0150-02
Use of anthracene oil for manufacture of formulations for various industrial uses <i>(mixtures which are mainly used as carbon black feedstock (CBF) in the EEA and a minor quantity to produce other mixtures)</i>	10 000 - 100 000	1.9 kg (9 PAHs)*	Authorisation partially granted (REACH/22/13/1) on 17/03/2022	0151-02
Use of anthracene oil for manufacture of formulations for various industrial uses <i>(carbon black feedstock and mixtures for export)</i>	10 000 - 100 000	0.993 kg (9 PAHs)*	Authorisation partially granted (REACH/22/14/1) on 16/03/2022	0152-02
Use of anthracene oil for manufacture of formulations for various industrial uses <i>(carbon black feedstock)</i>	1 000 - 10 000	0.8 kg (9 PAHs)*	Authorisation partially granted (REACH/22/12/1) on 16/03/2022	0153-02

* releases include PAHs from EC 266-028-2: Pitch, coal tar, high temperature (CTPHT) and anthracene oil

For these four applications for authorisation, the quantity of anthracene oil used to formulate creosote is not covered by the application because the upstream formulation step precedes a biocidal use and it is therefore exempted from the authorisation requirement⁹.

Based on the information from the applications for authorisations, there are thus no incorporation of the substance in articles in the EU/EEA. Imports of articles containing the substance may be still possible.

⁸ Search done 03/03/2021: <https://ec.europa.eu/docsroom/documents/44775> and <https://echa.europa.eu/applications-for-authorisation-previous-consultations>

⁹ Q&A 1027 (03/10/2018), available at: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1027>

Substance in article notifications

There are no Substance in Articles (SiA) notifications made under Article 7(2) for anthracene oil.

Submissions under the Waste Framework Directive (SCIP)

According to SCIP submissions (under Art. 9(1)(i) of the Waste Framework Directive) received by ECHA, anthracene oil is likely to be found in parts and accessories of motor vehicles/heavy machinery, medical instruments, base metal articles and plastic articles. Notably, anthracene oil can be present in plastic car body and AV system parts, and in the rubber of lawnmower tyres. AO can also be present in internal components of medical instruments and gas sensors as well as in thread sealant tape.

The presence of anthracene oil in other lubricants, greases, and oils and/or used in other articles/incorporated into other articles and in other articles made from copolymers of acrylonitrile-butadiene-styrene (abs) or rubber can not be excluded.

The most potential direct exposure for humans and environment is assumed from thread sealant tape and lawnmower tyres, where AO can be present up to 10%. While there is no knowledge about their manufacture in the EU, it is possible that imported articles of the aforementioned types contain AO.

The articles containing AO notified to the SCIP database differ from the registered uses.

Uses identified before the inclusion of AO in Annex XIV

Previously identified uses of anthracene oil which could lead to the incorporation into articles include (Germany, 2009):

- Impregnation agent (mostly as wood preservative, sometimes for ropes and sailcloth);
- Component in tar paints for special application (e.g. underwater corrosion protection);
- Component of waterproof membranes for roofing and other sealing purposes.

Information from REACH registrations

On 22 June 2022, there were 9 active registrations which include several registered intermediate and industrial end uses of anthracene oil. Two uses by professional workers and within industrial settings in the active REACH registrations, which can result in incorporation of anthracene oil into articles, are:

- Wide-dispersive use of paints, coatings and waterproofing materials;
- Use in the production of refractories.

Although the paints, coatings and waterproofing materials are mixtures, their use can result in incorporation of anthracene oil in machinery, equipment, vehicles, other transport equipment. Nonetheless, while the registrations do not specify the exact nature of articles treated by industrial and professional workers, internet searches for anthracene oil containing coatings reveals producers who sell AO containing coating and sealant system for e.g. heavy-duty corrosion protection products including a two-component epoxy system. According to the registration dossiers, anthracene oil is used in "End use of green refractory products (shaped and unshaped) including impregnated refractory products" and in the production of tempered shaped refractory product.

Other registered uses are not in the scope of this Article 69(2) screening report as the end products are not articles (e.g. the use of anthracene oil to produce certain type of electrodes which are not regarded as articles¹⁰, use as fuel, reductant in iron production, metal production, black cathode production etc.). There are also registered intermediate uses of anthracene oil to produce e.g. carbon black, which are not relevant to this screening report.

Information from external databases

Public database (Annex 1) searches indicated the following uses of anthracene oil which could lead to its inclusion into articles which contain or are:

- Paint, lacquers, varnishes, adhesives, binding agents;
- Machinery, special construction material, construction material (stone, cement);
- Manufacture of other transport equipment;
- Building and repairing of ships.
- Wood

Search via Google using keyword 'anthracene oil in coatings' revealed that anthracene oil is present e.g. in a heavy-duty coating for steel and concrete distributed by a globally operating corporation.

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, there are uses identified which 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.

In conclusion, the uses of AO in articles from all sources are:

- articles onto which paints, coatings, sealants, adhesives, binding agents and waterproofing materials are applied (e.g. machinery, equipment, vehicles, other transport equipment),
- refractory products
- articles in which lubricants, greases, and oils products are used (motor vehicles/heavy machinery, parts and accessories of mechanical machinery),
- articles where co-polymers and polymers of ABS (thermoplastic) and other rubber are used (eg lawnmower tyres and thread sealant tape),
- articles for construction made from cement or stone,
- articles of wood.

Uses in paints and refractories are mentioned by all the sources except SCIP while the other articles are only mentioned by some of the sources. Articles containing lubricants, greases and oils and articles made from plastic or rubber were indicated by the SCIP database. Cement,

¹⁰ Q&A 1195 (22/06/2016), available at: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1195>

stone and wood articles were suggested by the public databases. These uses were not 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.

B.2.4 Description of targeting

This report under Article 69(2) is targeted at the risk from uses of AO in articles throughout their lifecycle (including the waste stage), and whether or not such use should be restricted. Furthermore, targeting is based on the hazards for which the substance was included in 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 AO is presented in Table 4.

Index #	EC #	Classification	Specific Conc. Limits, M-factors	Notes	ATP inserted/updated
648-079-00-6	292-602-7	Carc. 1B (H350)	/	M	CLP00

Note M: the classification as a carcinogen need not apply if it can be shown that the substance contains less than 0.005 % w/w benzo[a]-pyrene (EINECS No 200-028-5).

Classification according to the Classification and Labelling Inventory

There have been two aggregated notifications to the C&L inventory¹¹ for anthracene oil. Carcinogenicity is not part of the notifications. In the registration dossiers, the additional endpoints are: Asp. Tox. 1, H304. 36 notifications cover the additional endpoints of Skin Irrit. 2, H315; Skin Sens 1B, H317; Repr. 2, H361; Aquatic Chronic 3, H412.

B.4 Environmental fate properties

According to the Member State Committee support document for identification of anthracene oil as a substance of very high concern because of its PBT and CMR properties (ECHA 2009), the PBT assessment of anthracene oil focuses on the assessment of its PAH constituents present in concentrations ≥ 0.1 %, such as anthracene (presence 3-25 %), fluoranthene (2-15 %), pyrene (1-10 %) and phenanthrene (10-35 %). Anthracene has been placed on the Candidate List due to its identification as a PBT substance (ECHA, 2008). Calculated half-lives in sediment for fluoranthene, pyrene, phenanthrene exceed 180 days, and a field study shows half-lives of 7.8,

¹¹ Accessed on 17/06/2021

8.5 and 5.7 years respectively. The P and vP criteria are fulfilled for anthracene, fluoranthene, pyrene, phenanthrene. Based on the log Kow of its constituent (in the range 3.84 to 5.20) anthracene oil has a high potential to adsorb to organic matter and is not or only little mobile in soil and sediment. According to the constituents' Henry's Law constants, anthracene oil is expected to be moderately volatile and volatilisation is not considered as a relevant route of distribution for anthracene oil. Anthracene fulfils the B criterion (ECHA, 2008). BCF values of several constituents of anthracene oil (fluorene, dibenzofuran, phenanthrene, fluoranthene, and pyrene) have shown to be > 2000 in several studies. Fluoranthene, pyrene and phenanthrene fulfil the vB-criterion with BCFs > 5000.

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 reliability¹².

B.5 Human health hazard assessment

In addition to being a PBT and vPvB substance, anthracene oil was included in Annex XIV based on its carcinogenic properties (Carc. 1B). This applies unless it can be shown that the substance contains less than 0.005 % w/w benzo[a]pyrene (EC No 200-028-5). In the four applications for authorisation, the anthracene oil contained less than 0.005 % w/w benzo[a]pyrene and consequently workers' exposure has not been assessed by RAC. No reference dose-response relationship has been derived by ECHA's Risk Assessment Committee (RAC) for this substance.

While there is no dose-response studies for anthracene oil, the corresponding values for 266-028-2: Pitch, coal tar, high temperature (CTPHT) can be used as a reference (Table 5) due to the similarity of these substances (benzo(a)pyrene being an indicator for both substances).

Table 5: 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 (c)

^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) = $0.001835 \times 8\text{h TWA BaP concentration in air } (\mu\text{g}/\text{m}^3) + 0.1729$
- urinary post-shift concentration of 1-OHP (µmol/mol creatinine) = $11.1 \times 8\text{h TWA BaP}$

¹² 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).*

concentration in air ($\mu\text{g}/\text{m}^3$) + 1.13

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

c Benzo(a)pyrene being one of the PAH4 and PAH8

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/EC₁₀) < 0.01 mg/l are available for the PAH constituents. The T criterion is fulfilled for anthracene, fluoranthene and pyrene.

B.8 PBT and vPvB assessment

The PBT assessment of anthracene oil focuses on the assessment of its four PAH constituents present in concentrations $\geq 0.1\%$, which are respectively identified as PBT (anthracene), vPvB (phenanthrene), PBT and vPvB (fluoranthene and pyrene). It is concluded that anthracene oil is a substance containing at least 16 % of PAH constituents with vPvB and/or PBT properties (ECHA, 2009).

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.

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 anthracene oil (Article 33(b)).

Under REACH, anthracene oil was proposed for SVHC listing by Germany on 03/08/2009, the substance was listed in the candidate list on 13/01/2010 (ED/68/2009) and included into Annex XIV in 2017 (Commission Regulation (EU) No 2017/999). The entries in Annex XIV for anthracene oil Authorisation set a latest application date of 4 April 2019 and a sunset date of 4 October 2020.

Under entry 31 of Annex XVII, anthracene oil (along with 8 other substances) shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood; furthermore, wood so treated shall not be placed on the market. Derogations apply.

As regards polycyclic aromatic hydrocarbons (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 that come into direct as well as prolonged or short-term repetitive contact with the human skin 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 anthracene oil in textiles (although it has a harmonised classification as Carc. 1B), but benzo[a]pyrene is prohibited above 1 mg/kg (0.0001 % w/w) (Appendix 12).

A proposal for an Annex XV dossier (restriction) of substances with harmonised classification as skin sensitizers 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. Although anthracene oil does not have a harmonised classification as a skin sensitizer, it is worth noting that it is self-classified in its registration dossiers as Skin Sens. 1B, 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)¹³, the Carcinogens, Mutagens or Reprotoxic substances at work Directive (Directive 2004/37/EC)¹⁴, as well as the Industrial Emissions Directive (IED, Directive 2010/75/EU)¹⁵ and Waste Framework Directive (Directive 2008/98/EC)¹⁶.

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

¹³ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and 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>

¹⁴ 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>

¹⁵ 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>

¹⁶ 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) 2017/997 and Directive (EU) 2018/851. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705>

weight (w/w) on the EU market have to submit information on these articles to ECHA, as from 5 January 2021.

A scientific report for evaluation of limit values for PAHs at the workplace has been published by ECHA¹⁷ on 10 May 2022 on request of the European Commission.

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

PAHs are subject to release reduction provisions under the Persistent Organic Pollutants Regulation¹⁸. 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 AO 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 anthracene oil is available on ECHA's website under EU Chemicals Legislation Finder (EUCLEF)¹⁹.

B.9.2 General discussion on releases and exposure

For this report only releases and exposure from articles are relevant.

As anthracene oil is a PBT and vPvB, emissions to the environment can be regarded as a surrogate for risk. No threshold can be derived due to its carcinogenic, PBT and vPvB properties. These properties are due to the presence of PAHs in AO. 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 possible²⁰. The content of PAHs in anthracene oil 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 only a few specific constituents, 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

¹⁷ Available at: <https://echa.europa.eu/oels-pc-on-oel-recommendation/-/substance-rev/69728/term>

¹⁸ PAHs are listed in Annex III, part B, of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).

¹⁹ <https://echa.europa.eu/substance-information/-/substanceinfo/100.084.153>.

²⁰ 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

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 6.

Table 6: 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 or 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.

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

Anthracene oil is used e.g. in two-component coating products to protect metallic structures in extremely demanding conditions such as in marine environments. It may be assumed that these products are mainly used by trained professionals but there are uncertainties and these products may be available for consumers as imported articles. Proper instructions and safety guidance should be available to consumers but there may still be risk of exposure during and after use.

There is a lack of information concerning residual concentration of anthracene oil in imported coated articles (it acts as a crosslinking agent). Thus, a conservative assumption would be to

conclude there is a chance for residual concentration leading to human exposure mainly via dermal route and to environment via releases of anthracene oil to soil and sediment.

Overall, little information is available on the releases of anthracene oil from coated articles. Large scale onsite applications of coating mixtures (i.e. to protect concrete, steel, pipelines, or as a road sealant or to waterproof roofs) are in the scope of authorisation but no applications for such uses have been submitted. It is unclear to which extent paints, coatings, sealants, adhesives, and waterproofing materials are applied in articles outside EU/EEA and if such articles could be imported in the EU/EEA.

The amount of anthracene oil that could be imported via coated 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.

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

As no new specific information was submitted in the call for evidence concerning uses or imports of AO in coatings incorporated into articles, a conservative assumption would be that imported coated articles may contain AO.

Uses in refractories

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

Based on uses identified before inclusion of anthracene oil in Annex XIV and on current registrations, Anthracene oil is used to produce shaped refractory products (e.g. bricks). Anthracene oil can be used to produce refractory articles either by mixing into a preparation, 'green' or by impregnation where it typically acts as a binder. As the refractory products are fired, anthracene oil is reportedly fully coalified. However, there is a lack of quantitative data concerning this.

It could be assumed that some residual anthracene oil remains in refractory articles. However, the amount as well as the availability of anthracene oil from the matrix are uncertain. Anthracene oil is used both inside and on the surface of articles, therefore it is assumed that possible residual Anthracene oil/PAHs would be available for dermal exposure. Refractory articles are used in high temperatures, but it is uncertain if Anthracene oil/PAHs would be emitted to air as industrial processes have differing levels of enclosure of the equipment where refractories are used and risk management measures in place. The end-of-life of the articles could also result in releases and exposure to humans and the environment. Thus, worker exposure to Anthracene oil/PAHs in articles could arise during the processing of the articles, e.g. when machining or assembling them, during their use e.g. as furnace lining, and while handling articles at their end of life (waste stage, recycling (Horckmans, 2019; Refrasort project²¹). There would also be potential for releases to the environment during the same steps, however the extent of it is uncertain as it

²¹ <https://cordis.europa.eu/article/id/197342-how-to-turn-refractory-waste-back-into-raw-materials>

depends on the level of enclosure and risk management measures in place. Furthermore, current tonnage information in registrations for this use cannot be relied upon, as most dossiers have not been updated after the sunset date. Nonetheless, in the absence of specific data, quantitative estimates of releases to the environment could be derived based on the existing tonnage and release factors using the default release factors presented in Table 6 (i.e. ERC 12a, 12b, 12c, as well as for the waste stage).

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. An OEL for PAHs is being prepared 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 Waste¹ 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 AO or PAHs from the uses of imported articles cannot be excluded. The existing legislative 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 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

Uses in articles containing lubricants, greases and oils

Anthracene oil is used in the manufacture of lubricants, greases and oils. These may be used e.g. in vehicles and their parts, and different mechanical machinery likely becoming an integral part of an article. As such, it could be accessible to consumers and be a source of dermal exposure. The use and disposal of articles where lubricants are incorporated can lead to releases to the environment. Since the call for evidence did not produce any new information concerning the use of AO in articles containing lubricants, the assumption of potential dermal exposure is still valid.

Uses in articles of cement, stone, wood, plastic or rubber

According to data sources used, anthracene oil is used in wood preservatives and thus may be incorporated into articles. While the use of AO to treat wood and the use of treated wood articles is affected by restriction entry 31 (see B.9.1.), dermal exposure to humans and emissions to environment from treated wood articles cannot be excluded.

There is a lack of specific data on the use of anthracene oil in cement or stone (e.g. specialised construction activities). But as above, this kind of use could lead to incorporation of anthracene oil into construction materials and surfaces which are a source of dermal exposure to consumers (public) and releases to the environment.

Notifications to the SCIP database indicate AO may be incorporated into plastic vehicle accessories imported into and produced in the EU and medical articles which are imported into the EU. In addition, the SCIP database indicates that AO is used in thread sealant tape and

rubber tyres of lawnmowers up to 10% which can potentially lead to releases to environment and dermal exposure for humans.

No new data concerning the use of AO in cement, stone, wood, plastic or rubber articles was submitted in the call for evidence.

B.10 Risk characterisation

Since anthracene oil is a vPvB and PBT-substance, RAC did not support a quantitative risk assessment in its assessment of the submitted applications for authorisation. RAC considered that emissions of anthracene oil are a suitable proxy for assessing risks to the environment and to humans exposed via the environment (ECHA 2020). This is consistent with previous restrictions on PBT and vPvB substances where only a qualitative assessment has been made. In contrast, RAC did not consider emissions from articles as the uses applied for did not include production of articles.

Carcinogenicity is also a relevant endpoint to consider unless data support a concentration of benzo[a]pyrene below 0.005 % w/w in anthracene oil. However, as this information would be difficult to obtain for uses in articles, a reasonable assumption is to consider as a worst case that any article containing anthracene oil would have to be assessed for carcinogenicity as well.

As no safe threshold limit can be established, it is considered that any presence of anthracene oil and PAHs due to the use of AO in articles, not already regulated under authorisation and other legislations, potentially poses a risk and should be further investigated.

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

According to 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'²², the adequate control route is not possible for a non-threshold substance (such as anthracene oil²³). 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.

²² https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf

²³ 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

Initially, no information on suitable alternatives were available (Germany 2009). The applications for authorisations were applied only for formulation for which an analysis of alternatives is unnecessary and thus only short analysis of alternatives documents were supplied, which did not contain any information for alternatives on potential downstream uses. [ECHA, 2020]

No further information on alternatives was 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 AO and PAHs due to the use of AO, in articles incorporating paints, coatings, sealants, adhesives and waterproofing materials, lubricants, greases and oils, dyed textile, leather and fur, articles made of polymers and co-polymers of ABS and rubber, cement, stone or wood 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 AO in articles should be considered as part of a larger investigation to address risks of PAHs in articles, including from other sources than AO, 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 AO/PAHs as Article 68(2) covers only carcinogenic, mutagenic and reprotoxic properties.

The reasons are given below:

Annex XV 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 identified risks. PAHs are hazardous constituents in AO which may be at the origin of risks from its use in articles and therefore, ECHA considers that a restriction shall target the presence of PAHs in articles to fulfil this criterion.

Other articles, not made using AO, 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 hazardous constituent PAHs in articles).

Practicality

Article 69(2) is targeted to presence of articles containing Annex XIV substances. As the production of articles with AO in the EU is now completely banned, as the sunset date is passed, and unless an authorisation has been granted²⁴, only imported articles remain of concern (as well as any articles placed on the EU market before the sunset date).

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

Monitorability

The monitoring of the result of the implementation of a restriction on AO/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 single PAHs originating from AO, against PAHs from other substances/sources. It may be feasible in cases to analyse the full spectrum of hydrocarbons and relate these to AO but only if there are not other sources for the constituents in the article. Therefore, a restriction on PAHs in articles would not enable reliable monitoring of the result of the effectiveness on release/exposure minimisation of AO only. Consequently, a restriction of AO 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 AO in articles should be considered as part of a larger investigation to address risks of PAHs in articles from all sources and not only AO.

In summary, ECHA concludes that the following Community-wide actions could be envisaged:

- Option 1: restriction on AO in articles; however for the reasons stated above this would not be effective, practical/enforceable nor monitorable.
- **Option 2 (The preferred option):** restriction on PAHs in articles. Further investigation is needed on risks related to PAHs in articles. This investigation should identify relevant PAHs as well as relevant articles, beyond the articles listed in this screening report, which is limited to AO but does not include other articles containing PAHs from incorporation of other substances into/onto articles. If this investigation shows that there are risks that are not adequately addressed (the releases of the substance from articles / exposure of the substance when present in articles are not minimised), 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.

ECHA also notes that there are uses of AO in the EU which are in the scope of authorisation but for which no applications have been submitted, as industry considers them out of scope of the authorisations. The incorporation of AO 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 AO in the EU are respected.

²⁴ For AO, no authorisation was granted which would have led to the production of articles. See section B.2.2.

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 Annex XV report was subject to a call for evidence from 17 September 2021 to 29 October 2021 after which no new uses were identified

Stakeholders were invited to provide information on:

- manufacture and uses of anthracene oil in articles (any missing uses);
- shaped and unshaped refractory products
- 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 AO in metallurgical smelting 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 AO/PAHs in articles, releases and exposure from the use, analytical methods, alternatives)

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

Only one comment was received from industry confirming the use of AO as an intermediate substance in an industrial use manufacturing fine chemicals without any incorporation into articles.

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 AO 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"²⁵ were also mentioned. The first one is not published yet but ECHA had access to preliminary results.

According to the "Intermediate Uses of PetCo Substances" report, there is a potential of carry-over of harmful constituents of AO from intermediate uses to downstream uses and products in

²⁵ Available at: <https://www.umweltbundesamt.de/en/publikationen/development-of-a-chemical-analysis-concept-for>

e.g. manufacture of carbon black. For some uses e.g. lubricants, the environmental releases may be significant.

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

H. Other information

Not relevant.

References

- ECHA (2020) The applications for authorisation received by ECHA on anthracene oil are available at <https://echa.europa.eu/applications-for-authorisation-previous-consultations>
- ComRef (2015) "Responses to comments" document. Document compiling comments and respective answers from commenting period 01/09/2014-01/12/2014 on ECHA's proposal to include anthracene oil in the 6th recommendation of priority substances for inclusion in the list of substances subject to authorisation <https://echa.europa.eu/documents/10162/ae19d948-d625-4b36-a333-c25190d601d4> and <https://echa.europa.eu/documents/10162/b3654c23-cb97-4a2a-a7b9-17ff792923c6>
- Germany (2009) Annex XV report - Proposal for identification of a substance as a CMR cat 1 or 2, PBT, vPvB or a substance of an equivalent level of concern. Anthracene oil. Submitted by Germany, August 2009, available at <https://echa.europa.eu/documents/10162/502f4a21-202d-1108-0cf0-753947a2891b>
- Germany (2016) Annex XV report - Proposal for identification of a substance of very high concern on the basis of the criteria set out in reach article 57. Benzo[def]chrysene (Benzo[a]pyrene), Submitted by Germany, February 2016, available at <https://echa.europa.eu/documents/10162/75eb6bd5-3375-4d68-854c-138fb87f0067>
- Germany (2017) Annex XV – Proposal for identification of a substance of very high concern on the basis of the criteria set out in reach article 57. Benz[a]anthracene. Submitted by Germany, August 2017, available at <https://echa.europa.eu/documents/10162/7dee6291-0995-4c31-8fef-b86a59336ffa>
- ECHA (2008) Member State Committee support document for identification of anthracene as a substance of very high concern (adopted 8 October 2008), available at <https://echa.europa.eu/documents/10162/f7c1321a-6709-40d6-b683-1fb870fb0ac4>
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- ECHA (2015) Background document for anthracene oil - document developed in the context of ECHA's 6th Recommendation for the inclusion of substances in Annex XIV (1 July 2015), available at <https://echa.europa.eu/documents/10162/0947b0ff-2152-46f8-9831-3ffb65beb1ed>
- RAC (2018) 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

UBA (2022)

Intermediate uses of petroleum and coal substances - a regulatory issue?
Environmental emission assessment of substances of very high concern
from petroleum and coal fractions in intermediates. Not published.

Annex 1

Database searches (27/05/2021) *	URL
Danish Chemicals in Consumer Products Database	https://vidensbank.mst.dk/v2/
Consumer Product Information Database CPID (USA & Canada)	https://www.whatsinproducts.com/
ChemSec SINLIST	https://sinlist.chemsec.org/
OECD Global Products Recall	https://globalrecalls.oecd.org/#/
Children's Safe Product Act Reported Data	https://hpcds.theic2.org/Search
Safety Gate	https://ec.europa.eu/safety-gate/#/screen/home
CPCAT	https://actor.epa.gov/cpcat/faces/search.xhtml
Substances in preparations in Nordic countries (SPIN database)	http://www.spin2000.net
KEMI Commodity guide.	http://webapps.kemi.se/varuguiden/Default.aspx
Health Canada	https://recherche-search.gc.ca/rGs/s_r?st=s&langs=eng&st1rt=0&num=10&cdn=health

*keywords used: Anthracene oil, EC: 292-602-7, CAS: 90640-80-5, 9H-carbazole; anthracene; phenanthrene, Anthracene oil < 50 ppm B[a]p, AOL, Anthracene Oil, BaP low, Anthracenový olej, AO I, Light anthracenic oil