



EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL

Directorate B – Protecting the natural environment
B.4 – Biotechnology and Pesticides

**ESSENTIAL USE APPLICATION
FORM FOR BIOCIDES**

1. MEMBER STATES AND EEA STATES

Austria	☐	Belgium	☐	Cyprus	☐	Czech Re- public	☐	Denmark	☐
Estonia	☐	Finland	☐	France	☐	Germany	☐	Greece	☐
Hungary	☐	Ireland	☐	Italy	☐	Latvia	☐	Lithuania	☐
Luxemburg	☐	Malta	☐	The Netherlands	☐	Poland	☐	Portugal	☐
Slovenia	☐	Slovakia	☐	Spain	☐	Sweden	☐	United King- dom	☐
Iceland	☐	Norway	☒		☐		☐		☐

2. ACTIVE SUBSTANCE

2.1. Common name	Pine tar / Pine wood tar
2.2. EC and/or CAS N°	EC no. 232-374-8, CAS No. 8011-48-1
2.3. Molecular and Structural formula (including details on isomeric composition) – molecular mass	Tar, a complex combination distillate containing thousands of substances (one estimate is up to 8000-15000 substances), produced by the high temperature carbonization of pine wood in anoxic conditions (dry distillation). It consists primarily of aromatic hydrocarbons, tar acids and tar bases (Simomaa et. al 2000, Lehtonen & Hotti 2001, Egenberg 2003). Components of tar vary according to the pyrolytic process (e.g. method, duration, temperature) and origin of the wood (e.g. age of pine trees, type of soil and moisture conditions during tree growth). The choice of wood, design of kiln, burning and collection of the tar can vary from burning to burning. Only stumps and roots of pine can be used for traditional production of pine tar. Wood cellulose creates at 240-375 °C aliphatic hydrocarbons such as fats and their esters and paraffins in the tar. Lignin creates aromatic hydrocarbons such as phenols, cresols and guaiacols at 350-500 °C. Pine tar also contains turpentine and resin acids formed from pine resin. Content of phenolic compounds in the pine tar samples analysed has been about 2.4–6.3% w/w. Pine tar contains several kinds of polycyclic aromatic hydrocarbons (PAHs) because pine tar is produced by a pyrolytic process in "unfavourable" conditions where PAHs are known to be formed. Duration of the distillation at 300-400 °C seem to affect the PAH content of wood tar. The higher the temperature in the kiln and the more reduced the firing, the more aromatisation of the tricyclic components will take place. However, a part of the PAHs will be emitted to the air during production (as local, intermittent emissions) and will not have effect on the final product. Traditionally produced pine tar contains 8-18% w/w volatile substances. The distillation temperature starts from 200 to over 400 °C. The tar fractions from an early stage of the burning are very different from the fractions from a later stage of the burning probably as a result of the increase in temperature and the relatively reducing conditions under which the production takes place. Light tars are produced from 280 °C above and heavy tars above 350 °C. Maximum production of acid distillates is achieved at 270 °C and above 350 °C only little acids are formed. Some details of pine tar components are given in point 2.5. The composition of pine tar is instable because its composition changes in chemical reactions over time, e.g. through polymerisation. Sometimes up to 40-50% of pine tar is oligo- or polymeric material from resin acids and other diterpenes or from phenolic material.
2.4. Method of manufacture (in brief terms)	Pine wood gives tar in quantities of about 7% w/w of the dry wood weight. Pine tar is produced by traditional or more industrial methods. The traditional manufacturing method is a kiln made of stone or wooden stocks. In the latter case the stocks are both the building material of the kiln

and starting material for the carbonization process. Dried stumps and roots of pine cut in pieces can be used for this production. The wood is stapled in radial form from the centre outwards in the kiln. It has to be covered carefully by turf before the burning. The tar is collected through a hole in the middle at the bottom of the kiln. The burning takes several days at <100-390 °C and has to be thoroughly surveyed.

Another manufacturing method is the retort process which is a more modern yet about 100 years old version of the traditional way of producing tar. The kiln is then a closed iron basin called retort ("tar oven") which is heated externally without letting the pine wood inside the retort to burn. The process parameters can be better controlled than in the traditional methods. Distillation temperature may increase over 400 °C in the end.

2.5. Specification of purity in g/kg or g/l as appropriate

Main components of traditional kiln made pine tar:

- resin acids and aldehydes (e.g. dehydroabietic acid, abietic acid, palustric acid, pimaric acid) 19% w/w
- decarboxylated resin acids and alkylphenantrenes (e.g. retene) 7.5-9.5% w/w
- fatty acids (mainly C14-18) 8% w/w
- phenols (e.g. methyl- and ethylguaiacol, guaiacol, cresols, phenol) <5% w/w
- monoterpenoids (e.g. alpha-pinene, 3-carene, limonene, camphene) <5% w/w

Main components of pine tar made in retort process:

- monoterpenoids 18% w/w
- resin acids and aldehydes 16% w/w
- decarboxylated resin acids and alkylphenantrenes 13% w/w
- fatty acids 7% w/w
- phenols 6% w/w

Note 1: the percentages given above are from very few analysis and therefore not representative but only indicative. See point 2.3 above for a general description of the full composition. Note 2: Retort tar contains higher contents of components with low boiling point such as turpentine compared to traditional kiln made tar. Retort tar contains also hydrocarbons with higher C:O and C:H ratios, and higher proportion of double bonds compared to traditional pine tar, indicating higher proportion of reduced firing. Note 3: 1 % w/w equals to 10 mg g⁻¹.

2.6. Identity of impurities and additives – including stabilisers

No specific impurities can be listed separately but they are part of the complex combination distillate (c.f. point 2.3).

Wood tar distillation fraction produced at 300/350-450 °C is water insoluble, viscous and is called A-type tar. Wood tar fraction produced at 250-350 °C is water soluble, more liquid and is called B-type tar. The water soluble wood tar distillation fraction contains in addition to B-type tar also methanol, acetic acid and acetone. Raw wood tar is a mixture of A and B type tars and B-type compounds are separated e.g. by storing the raw tar for a year. Therefore, the content of the A and B fractions in the final product vary according to when during the burning the tar is drained off from the kiln and its age.

Composition of the tar will also vary from batch to batch since the choice of wood, design of kiln, burning and collection of the tar can vary from burning to burning.

2.7. Origin of substance (in case of a natural substance)

Pine tar is not a natural substance because it is modified during the pyrolytic process.

2.8. Physical chemical properties in accordance with Annex IIA, Point III, to Directive 98/8/EC, as appropriate

The colour of the tar is in varying shades from black to brown. The flashpoint may be around 150 °C. The density >1 (maybe around 1.033 to 1.09). Pine tar has a strong distinct odour and is in practice not water soluble (contains only 2 - 6% w/w water soluble substances). pH in water solution is 3-4. Viscosity is about 980-9160 mm²/s ranging from low viscous to high viscous oil.

2.9. A summary or toxicological

Toxicological information

The "Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) concerning wood tars and wood tar preparations"

and ecotoxicological information for the substance

(SCCNFP/0646/03) focused on the carcinogenic and genotoxic potential of pine tar and other wood tars. The analysis was based on:

- 1) The composition of pine tar: PAH-compounds, ca. 50 ppm (0.0005%), comprising e.g. benzo(a)pyrene (5.3 to 9.7 ppm) which is classified as a cat. 2 carcinogen, cat. 2 mutagen and cat 2 reprotoxin.
- 2) Mutagenicity/Genotoxicity, in vitro: Pine tar resin have not been found to induce mutations in *S. typhimurium*. Guaiacol has induced CSE in human lymphocytes in vitro.
- 3) Carcinogenicity . A) Animal studies: The carcinogenicity of pine tar (with 48 ppm BaP) and other tar-containing skin drugs was investigated with mice (Hirohata et al. 1973). Pine tar induced not only skin papilloma, but also skin squamous carcinoma. It was also concluded that the frequency of skin tumours increases nearly linearly with the concentration of benzo(a)pyrene in the preparations. Many of the PAHs known to exist in wood tars have been evaluated by IARC with the conclusion that there is sufficient evidence for carcinogenic effects in animals. B) Human studies. No data were available. Several studies have demonstrated tumour induction in relation to tar and creosote (coal tar), in most cases the latter. However, it is unclear whether some studies possibly also involved wood tar or wood tar preparations. The SCCPNFP concluded that wood tar preparations induced both benign and malignant skin tumours in mice, possibly by non-threshold mechanism. The dermal route was relevant here.

Other studies/data

According to Elliot D.C. (1987) pine tar induced carcinomas in animal tests. This carcinogenic potential increased as a function of the temperature of production. This study has not been critically evaluated.

The chemical composition of Finnish pine tars gives some information on their toxicity. However, many of the thousands of components have not been identified. Some of the major components have been classified as harmful (Xn) or sensitising. The concentration of PAHs in the Nordic pine tars has not been determined although they are known to exist in pine tars. The carcinogenicity of the pine tars has not been evaluated. Based on the available information, carcinogenicity of the pine tar cannot be excluded.

Ecotoxicological information

There is very sparse ecotoxicological information available on pine tar. The resin acids of pine tar are acutely toxic to aquatic organisms in concentrations below 1 mg/l where they have caused e.g. histopathologic changes in liver and harmful effects on erythrocytes in fish. For example, abietic acid has a LC50 for rainbow trout of 0.7 mg/l, dehydroabietic acid LC50 for rainbow trout of 0.77 mg/l and pimaric acid LC50 for rainbow trout of 0.33 mg/l.

Some polycyclic hydrocarbon components of pine tar are classified as dangerous for the environment (N, R50-53 or N, R50).

Some relevant information can be found from the environmental risk assessment of certain creosote compounds the log octanol-water partitioning coefficient (logKow) of which is 0.5-2.0. These are hydrocarbons containing one aromatic ring such as cresols and phenols. Their boiling point is about 175-210 °C, they are volatile, very water soluble, mobile in the soil (Koc 2.8-148), biodegradable, and partly potentially bioaccumulating. Their aquatic toxicity is moderate in acute exposure (EC50 >8.3 mg/l) and slight in chronic exposure (NOEC>0.75 mg/l, LOEC >0.2 mg/l).

See point 3.5 for exposure and risk assessment.

3. AVAILABLE INFORMATION ON THE ESSENTIAL USE

3.1. Product type and use(s) for which the derogation is required

Pine tar is suspected to be a surface treatment wood preservative in Product type 8.

Pine tar produced in traditional kilns is used to preserve protected historic buildings for instance churches and other object of cultural interests in Norway. The production volume from the traditional method is not sufficient to cover the demand of essential uses of pine tar and retort produced pine tar is also used in some extent for these essential uses. The application of pine tar is needed to keep the surfaces, the materials and the colours of the buildings in good condition and in their original appearance. In those places where wood tar was traditionally used such as timber buildings especially on country side, the use of other products to preserve the wooden historic buildings is highly unsafe and can lead to the destruction of the buildings through

cracking of the wood etc. (see also Section 5.2).

Pine tar produced in traditional kilns is also used to preserve traditional arts and crafts such as traditional wooden boats in Norway.

3.2. Method(s) of application

Pine tar is normally applied by a big brush. It is recommended to apply a thick layer or several layers of tar to protect the wooden buildings/objects from water penetration and degradation by weathering (including UV-light).

3.3. Number and timing of applications

Pine tar has to be applied every 1-25 years to give the surface sufficient protection depending on the tar quality, building and construction details, the orientation and the local conditions.

3.4. Classification & Labelling

Pine tar is proposed to be classified as "Harmful by inhalation, in contact with skin and if swallowed. Irritating to eyes, respiratory system and skin. May cause sensitization by skin contact. Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment."

Xn, N; R20/21/22, R36/37/38, R43, R51-53.

Some polycyclic and other hydrocarbon components of pine tar are classified as dangerous for the environment (N, R50-53; N, R50 or R51-53). Their concentration sum is above 2.5% and will cause pine tar to be classified as dangerous for the environment: N, R51-53.

Classification of some components of pine tar according to Annex V of Directive 67/548/EEC or available information:

Turpentine/turpentine oil, especially C10-terpenes and other terpenes (which may be more than 5% in retort pine tar) are classified as Xn N, R10, R20/21/22, R36/38, R43, R51/53, R65.

Resin acids and esters with glycerol (which may be more than 15% in pine tar) are classified as Xn; R20/21/22. Abietic acid, dehydroabietic acid and pimaric acid are classified as N, R50.

Pure phenol is classified as T; R24/25; C, R34. Cresols (which may be more than 1.3% in pine tar) are classified as T; R24/25; C, R34. Limonene is classified as Xi, R10; R38, R43; N, R50-53.

3.5. Available data on effects on human or animal health and the environment (including exposure and risk assessment and proposals for risk mitigation) from the use

The following are the exposure and risk assessments for human health and the environment made on the basis of available data which are sufficient at this stage for the prolongation decision on the essential use. However, more detailed evaluation can be done after the corresponding assessments have been made for other surface treatment wood preservatives in the BPD Review Programme.

Human health

Pine tars from different sources are heterogeneous in composition, due to variations in the starting materials and especially in production processes. The significance of the differences in the composition of tars in relation to health effects are not known, and they are not discussed here.

Information exists on occasional dermal reactions on the hands of users of tar. These have been regarded as signs of irritation, but sensitisation may also have contributed to the symptoms. Fragmentary data on acute respiratory symptoms have been usually related to indoor use without protection which can be regarded as a misuse of tar. Part of these uses are not related to wood preservation. Some of the claimed health effects may have resulted from use of coal tar sold as pine tar. Sometimes unknown hydrocarbons have been added to commercial pine tars. During the long history of production and use of pine tar for a variety purposes, including medicinal and veterinary uses, carcinogenic or other serious health effects in humans or animals have not been reported in Norway.

No exposure measurements have been carried out in Norway.

Typical use and exposure scenarios, primary exposure:

Pine tar is applied on the external side of a building using a (often long-handled) brush, a spatula or a rag, by a professional worker wearing a personal protective equipment (PPE; a protective clothing, gloves, shoes and a hat), for a period of one month per year. The worker is normally not the producer of tar. Therefore there is no cumulative exposure from manufacturing. For exposure, the dermal route is the most relevant, and the use of PPE needs to be emphasised.

For the normal outdoor conditions, exposure by inhalation is not considered very relevant.

Application of tar on traditional boats and ships is comparable to treatment of historical buildings. However, vessels may sometimes be treated with tar in indoor conditions. In such

situations personal respiratory protective equipment and good ventilation are essential. Treatment of traditional small boats is sometimes done by a non-professional, typically the owner of the boat. Although accidents are rare, fire safety needs also to be taken into account, especially if tar has to be liquefied by warming up (up to 60 °C) for use. Open fire must not be used. Secondary exposure: After application, tar will harden to some extent dependent on temperature and light, and re-release of the most volatile components will rapidly diminish. Only infrequent secondary exposure situations are expected to occur during or after application of tar. Prevention of dermal contacts is essential, especially if the tar is still soft.

Environment

Pine tar treated buildings will cause local emissions of pine tar components to the surrounding soil. Pine tar treated wooden boats will cause local emissions similar to antifouling products to lakes, coastal areas and other such water courses. Available biocides emission scenarios for wood preservatives and antifouling products could be used for such exposure assessment but the data on leaching rates of pine tar components is lacking. Therefore, a quantitative risk characterisation for these environments cannot be made. However, possible adverse effects to soil are assessed to be occasional local ones because pine tar treated buildings are sparsely located. Adverse effects to the aquatic environment in marinas and other similar locations are considered to be unlikely because traditional pine tar treated wooden boats are a minor fraction of the pleasure boats in Norway and the application factors are therefore very low. Emissions to air occur especially during production of pine tar.

Possibilities for risk mitigation

- Products should be labelled correctly, including proper R and S phrases.
- Use of pine tar should be instructed in more detail, emphasising significance of protective equipments and correct working habits.
- The proposed risk mitigation measures can be made more detailed on the basis of data made available under national provisions.

3.6. Information on efficacy

It is difficult to conclude if pine tar is an effective surface treatment wood preservative and as such should be regarded as a biocide.

A test by the laboratory "Mycoteam A.S." (Mattsson, J; Holøs, S. B. & Whist, C. M.) from 1995 shows that pine tar gives a little, but very low protection towards fungi and algae compared to mordant oil and also compared to birch tar. From this test they conclude that other properties of pine tar as water protecting effect probably are more important for its ability to protect the wooden objects.

The article from Poland "Application of Wood Tars in Wood Protection" by Lutomski, K , 1997 shows among others that softwood tars such as pine tar have less antifungal toxicity than hardwood tars and much less than creosote oil. The article also states that stripping the softwood tars of the more volatile compounds decreases even further the already low antifungal toxicity of these tars.

The decay test by the Finnish VTT from 1981 shows that pine tar surface treatment did not inhibit the growth of brown rot fungus *Gloeophyllum trabeum*, and protection effect was non-existent (Kaila, Vihavainen & Ekbohm, 1987, p. 67).

In the test carried out by the VTT in 2004, the effect of various pine tars added as 0.5 % into the malt agar medium varied according to the fungus. The most sensitive to pine tars was the brown rot fungus *Coniophora puteana*, the radial growth of which slowed down considerably. The effect on the growth rate of white rot fungus *Coriolus versicolor* was very low. The commercial boron containing surface treatment wood preservative product tested inhibited totally the growth of *C. puteana* and *C. versicolor* and decreased more than pine tars the growth of *Aureobasidium pullulans*. The commercial zinc containing surface treatment wood preservative product inhibited totally the growth of *C. puteana* and decreased very strongly the growth of *C. versicolor* and *A. pullulans*.

In another VTT test from 2004, where a piece of pine tar treated veneer was placed on malt agar medium in Petri dish at the same time of inoculation with fungus, the effect of pine tars on the growth rate of mycelium was very low. No inhibition zones are observed. The mycelium of fungi tested (*Coniophora puteana*, *Coriolus versicolor* and *Aureobasidium pullulans*) covered

the dish, the growth on the treated veneer was slowed down only with *Coniophora puteana*. The commercial boron containing preservative product induced inhibition zones and zinc containing product slowed down the growth of fungi. Further studies showed that rot infested, old pine tar treated church roof shingles contained brown and white rot fungi and bluestain fungi. In order to test the efficacy of pine tar not only in laboratory tests but also in more normal conditions of use the growth of different fungi on pine tar treated wood was also studied outdoors by the VTT. Wood pieces having white rot and bluestain fungi growing on them were treated with 100% pine tar on the side where fungi were growing. Dried wood specimen were then exposed outdoors to rain and sun for a few days in August 2004. The fungi were observed to grow through the thin pine tar layer. The growth of decay fungi was abundant and there was also some bluestain fungi growing through the pine tar layer. Therefore, pine tar treatment did not have an effect on the growth of fungi in practise. However, a comparison with a typical commercial wood preservative as a control was lacking. Earlier e.g. white and brown rot have been found in old pine tar treated shingles after the wood has become wet.

To clarify the questions remaining from previous pine tar efficacy studies a new efficacy test with representative Nordic pine tar samples is underway at Sveriges Provnings- och forskningsinstitut (SP) in Sweden funded by the Nordic Council of Ministers, Miljøstyrelsen in Denmark and Directorate of Cultural Heritage in Norway. The test is done according to standard EN 113 (CEN 1996-09-18): Test method for determining the protective effectiveness against wood destroying basidiomycetes - Determination of the toxic values) after a superficial treatment and "ageing" according to method EN 84 (EN 84 (CEN 1997-01-22): Accelerated ageing of treated wood prior to biological testing – Leaching procedure. The final report is planned to be ready in May 2006. On the basis of previous efficacy study results it is expected that this test will finally verify that pine tar does not have sufficiently biocidal efficacy at 'normal conditions of use' to be a biocidal product.

Further conclusions on the efficacy of the pine tar products can also be made after the efficacy assessment has been made for other surface treatment wood preservatives in the BPD Review Programme.

4 - JUSTIFICATION OF THE ESSENTIAL USE

4.1. Significance of the harmful organism

Efficacy of pine tar for wood treatment is mainly based on physically blocking the porous structure of the wood material and making the material water proof. The treated wood can resist wood destroying fungi because the water concentration in the wood is kept low enough. Pine tars may have a slight biocidal effect on some fungi species. If the wood stays moist due to rainwater etc. fungi will start to grow and rot or discolour the wood leading to its destruction. Principal harmful organisms on such wood are brown rot fungi (e.g. *Coniophora puteana*, *Gloeophyllum trabeum* and *Poria placenta*), white rot fungi (e.g. *Coriolus versicolor*) and moulds and bluestain fungi (e.g. *Aureobasidium pullulans*). On the other hand, the slight biocidal effect of some pine tars has no practical significance because only a thick pine tar coating layer is an effective protection for the wood. If the pine tar layer is cracked or otherwise defective the wood will get moist and fungi will attack the wood through the cracks.

Wood preservation is not the objective in treatment of traditional wooden boats with pine tar. Without a pine tar treatment water will get soaked into the hull and the boat will sink.

4.2. Importance of the intended use and estimated scale of use - maximum quantity of active substance per year

The major part of traditionally produced pine tar currently produced in Norway is used for objects of cultural interests. One treatment of a stave church requires approximately 500 litre pr. year in a three subsequent year treatment to be protected. Churches with wooden roof can require up to 2000 litre . There are 28 stave churches in Norway and several churches with wooden roofs. In addition, other historic and traditional wooden objects such as buildings and constructions of vernacular architecture and traditional wooden boats have to be treated with pine tar. The total essential use demand in Norway has been roughly estimated to be a maximum of 50 000 litre a year.

Pine tar is also to some extent exported from Norway to other countries within Europe for use on wooden objects.

4.3. If the essential use is not permitted, what would be the consequences for health, safety, protection of cultural

heritage or the functioning of society (including cultural and intellectual aspects)?

According to the second Review Regulation the placing on the market of pine tar as a biocidal active substance for wood preservation is no more possible after 1st September 2006. However there is still an open question whether pine tar used as described is to be considered as a biocidal active substance.

In Norway the most severe impact will be that a key part of our national heritage, stave churches, among them Urnes stave church on the World Heritage List, and other protected buildings and traditional wooden objects such as wooden boats, could no longer be treated with wood tar. There are no suitable alternative chemicals for the treatment of such wooden objects. If these cannot be treated with pine tar, decay gradually will take place and in the long run the objects will be ruined completely. The possible destruction of the valuable objects once the ban has entered into force is not acceptable. (See also Section 5.2).

The traditional way of producing of pine tar is in itself of great cultural value and should as such be allowed to continue.

The historical value of pine tar and pine tar production is significant in Norway. From the point of view of historical and cultural authenticity, no substitute for pine tar exists. The loss of cultural heritage objects and cultural environment as a consequence of destruction or lacking maintenance cannot be accepted.

4.4. Need for the biocidal product / active substance in resistance or other pest management programmes (for example integrated pest management)

Not applicable to pine tar because it is not used in resistance or other pest management programmes.

5 - WHY THE USE OF THIS ACTIVE SUBSTANCE IS ESSENTIAL

5.1. Active substances currently used [elsewhere in the EU/worldwide) to control the problem described in 4.1. and their approval/authorisation status

About 15 active substances of those about 37 substances that will be evaluated in the BPD Review Programme exist currently on the market for general surface treatment of wood against wood destroying fungi. However, these substances do not provide the very important physical blocking of the porous structure of the wood material making the material water proof which pine tar does. The authentic colouring of the wood and protection of degradation due to light of the wooden objects is also not possible with these alternatives. Furthermore, these cannot substitute pine tar because from the point of view of historical and cultural authenticity, no substitute for pine tar exists (c.f. point 4 above).

5.2. Evidence that there are no available technically and economically feasible alternatives or substitutes that could be acceptable from the standpoint of environment and health

Pine tar stays soft also after the wood has been treated and is the only chemical that can be used for such treatment. Norwegian and Finnish experts have unsuccessfully tried to find a substitute for pine tar for many decades as part of work to improve the performance of pine tar treatment where also less expensive treatment methods were tested that were wished to be equivalent with pine tar treatment. Alternative chemicals such as coal tar make the wooden shingles and panels hard and crack. The cracks in the wooden roof let rain water enter the building and damage it. Neither is the use of creosote oil possible due to its chemical and other properties. Once tarred surface cannot be treated with any other substances due to either their reaction with tar or their structural behaviour. The use of other products (e.g. epoxy resins) to coat surfaces of historical buildings and objects would also destroy their look.

European countries are State Parties of the Unesco World Heritage Convention. Instructions and guidelines given in "Bernard M. Feilden and Jukka Jokilehto, 1993. Management Guidelines for World Heritage Sites. ICCROM, Italy." should be followed in the maintenance and conservation of these sites. On its p. 70-71 guidance is given on treatments related to authenticity in workmanship and maintenance: "The repair of heritage resources using compatible traditional skills and materials is of prime importance....In the case of vernacular architecture, which often consists of short-lived or vulnerable materials... the same type of materials and traditional skills should be used for the repairs and restoration of worn and decayed parts."

According to the recommendations and guidelines of ICCROM (International Centre for the Study of the Preservation and restoration of Cultural Property) and ICOMOS (International Council on Monuments and Sites) International Scientific Wood Committee Principles for the Preservation of Historic Timber Buildings the surfaces has to be treated

on a like-a-like basis. "Craftsmanship and construction technology, including the use of dressing tool or machinery, should correspond with those used originally. Surface finishes ... should be duplicated as far as possible". Similar recommendations come also from the European Council Granada Convention 1985.

The Competent Authority for these conventions, the Norwegian Directorate for Cultural Heritage, very strictly recommends the protected buildings to be treated with pine tar in order to protect the buildings from decay. For some protected objects even only traditionally produced pine tar is accepted to be used. In conclusion, these essential uses of pine tar cannot be replaced by alternative materials for economic and cultural reasons and substitution is impossible also for technical reasons.

6 - PROPOSED PLAN FOR A MORE PERMANENT SOLUTION

6.1. Evidence of a plan to submit a dossier for the evaluation and inclusion of the active substance in one of the annexes to Directive 98/8/EC

It is expected that the essential use derogation for pine tar is needed only until an agreement has been achieved on whether pine tar is not a biocidal active substance on the basis of the ongoing efficacy study according to CEN 113. The current estimate is that this will be clarified by year 2007. Therefore, this application is valid only until a possible agreement on exclusion of pine tar from the scope of Directive 98/8/EC.

A dossier submission for the evaluation and inclusion of pine tar in Annex I to Directive 98/8/EC has not been regarded as a feasible solution because the costs of compiling the required dossier are too high compared to the volumes of pine tar used on the limited group of objects of cultural and historical interest. The traditional method of manufacturing pine tar means that there are many single producers, the volumes per producer are very small and type and composition of the products may vary a lot. Data generation for such products, application for authorisation and evaluation of such complex mixtures is not possible in practice. On the basis of current principles of risk assessment for biocides complex hydrocarbon mixtures such as pine tar are evaluated on the basis of similar hydrocarbon groups (or "blocks") in the mixture since hydrocarbons of similar structure will have similar physico-chemical properties and similar distributions and fates within a given environment (c.f. the Hydrocarbon Block Evaluation Method in the Technical Guidance Document on risk assessment, Annex IX to Part II). In pine tar at least five different hydrocarbon blocks need to be tested and evaluated. This means that the data generation costs would be many times higher than for a normal biocidal active substance. In addition the variation between the "hand-made" production batches of pine tar would need to be addressed in the dossier and evaluation. The volumes of pine tar used may seem to be relatively high but it should be noted that the product contains 100% of the substance of which the specific biocidal activity very low, if any in practice.

Proposed plan for a more permanent solution

As from the point of view of historic and cultural authenticity no substitute for pine tar exists, the only permanent solution for this pine tar essential use problem is to amend the Directive by adding a derogation procedure for example to Art. 15 of the Directive (98/8/EC) for biocidal products intended for protection of objects of cultural and historical interest. This is needed only if exclusion of pine tar from the scope of Directive 98/8/EC cannot be proven by inefficacy. The current derogation provisions from normal authorisation of biocidal products in the Biocides Directive do not include biocidal products intended for protection of objects of cultural and historical interest. In order to be able to preserve such objects with traditional biocides also in the future, the current derogation provisions on temporal authorisation in the Biocides Directive Art. 15.1 should be expanded to cover this new proposed derogation. The best way to do this could be to add a new paragraph to Art. 15 with comparable provisions to Art.15.1 but amended to enable a Member State to authorise a biocide product necessary for preservation of objects of cultural and historical interest. In justified cases such objects could be for example old traditional buildings, museum pieces of vulnerable materials or traditional wooden boats.

A similar kind of derogation for purposes of cultural and historical interest has been integrated in the VOC Directive (Limitation of Volatile Organic Compounds 99/13/EC). The text of the special considerations clause reads: "For the purposes of restoration and maintenance of buildings and vintage vehicles designated by competent authorities as being of particular historical and cultural value, Member States may grant individual licences for the sale and purchase in strictly limited quantities of products which do not meet the VOC limit values laid down in Annex II." (ref: Art. 3.3 of Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC)

This amendment of the Directive could be done in the framework of a substantial revision of the Directive following presentation by the Commission of the 10-year report called for in Article 18(5) of the Directive in 2007 - if essential uses of pine tar will be allowed to be continued until May 2010.

6.2. Any outline of work carried out to develop an alternative or substitute to the active substance

The only chemicals similar enough to pine tar are creosote oil and other coal tar distillates. They have been evaluated as alternatives to pine tar but were not found suitable (see point 5.2).

7- OTHER INFORMATION

- E.g.:
- Steps that are being taken to minimise the proposed uses
 - Steps to minimise the emissions and human exposure associated with the proposed uses and waste management related to the biocidal product
 - Acceptability of the active substance in light of the criteria in Annex VI of Directive 98/8/EC

Steps that are being taken to minimise the proposed uses, and the emissions and human exposure associated with the proposed uses and waste management

Such steps have been considered only little so far because the traditional uses of pine tar has not required such evaluation. Proposed uses of pine tar cannot be much minimised because it is the only appropriate application for the conservation and maintenance of certain types of traditional objects and buildings.

- The products should be labelled correctly, including proper R and S phrases.
- Use of pine tar should be instructed in more detail, emphasising significance of protective equipments and correct working habits (e.g. outdoor use and avoidance of inhalation of fumes of product, and avoiding of skin contact).
- National provisions to control the biocidal essential uses will be applied during the transitional period of the Directive. The proposed risk mitigation measures can be made more detailed in national approval decisions for essential use on the basis of further data made available in applications under such national provisions.

Acceptability of pine tar in light of the criteria in Annex VI of directive 98/8/EC

This evaluation can be done only in very general terms giving some indications on acceptability of pine tar because data on detailed composition of pine tar and its variation with different manufacturing conditions, and data on the toxicological and ecotoxicological effects of pine tar are lacking.

Human health

The conclusion of the SCCPNFP (i.e. "wood tar and wood tar preparations contain genotoxic carcinogens – and pose a health risk. Wood tar preparations induced both benign and malignant skin tumours in mice, possibly by non-threshold mechanism") concerned the use of wood tars in cosmetic products. The relevance of the conclusion with respect to pine tar as a wood preservative is unclear due to different exposure patterns and to different compositions. As the pine tars contain minor amounts of PAH's, the carcinogenicity of the tar cannot be excluded. However, there are no reports on carcinogenicity or other serious health effects in humans or domestic animals. The dermal or inhalatory reactions that are likely related to the harmful, irritating, or sensitising components have been occasionally observed. After application, no significant exposure to the painted surface is normally to be expected.

Some pine tar batches might exceed the maximum concentration limit for water extractable phenols set in the Creosote Directive (Commission Directive 2001/90/EC). It requires that the creosote to be placed on the EU market should contain water extractable phenols at a concentration of less than 3 % by mass.

Based on the available information on the toxicity and exposure, pine tar can be regarded as an acceptable substance for essential use wood preservation in outdoor conditions, provided that the substance is properly labelled and used.

Environment

The resin acids of pine tar are acutely toxic to aquatic organisms in low concentrations. Some polycyclic hydrocarbon components of pine tar are classified as dangerous for the environment. However, a quantitative risk characterisation for the environment cannot be made due to lack of data. Adverse effects to the environment are considered to be unlikely or occasionally very local.

Other aspects

A comparative assessment according to Art. 10.5 of the BPD cannot be made because no substitute for pine tar exists in these essential uses.