



**EUROPEAN COMMISSION**  
ENVIRONMENT DIRECTORATE-GENERAL

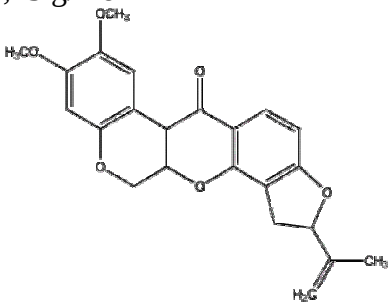
Directorate B – Protecting the natural environment  
**B.4 – Biotechnology and Pesticides**

**ESSENTIAL USE APPLICATION**  
**FORM FOR BIOCIDES**

**1. MEMBER STATES AND EEA STATES**

|           |                          |          |                                     |                 |                          |                |                          |                |                          |
|-----------|--------------------------|----------|-------------------------------------|-----------------|--------------------------|----------------|--------------------------|----------------|--------------------------|
| Austria   | <input type="checkbox"/> | Belgium  | <input type="checkbox"/>            | Cyprus          | <input type="checkbox"/> | Czech Republic | <input type="checkbox"/> | Denmark        | <input type="checkbox"/> |
| Estonia   | <input type="checkbox"/> | Finland  | <input type="checkbox"/>            | France          | <input type="checkbox"/> | Germany        | <input type="checkbox"/> | Greece         | <input type="checkbox"/> |
| Hungary   | <input type="checkbox"/> | Ireland  | <input type="checkbox"/>            | Italy           | <input type="checkbox"/> | Latvia         | <input type="checkbox"/> | Lithuania      | <input type="checkbox"/> |
| Luxemburg | <input type="checkbox"/> | Malta    | <input type="checkbox"/>            | The Netherlands | <input type="checkbox"/> | Poland         | <input type="checkbox"/> | Portugal       | <input type="checkbox"/> |
| Slovenia  | <input type="checkbox"/> | Slovakia | <input type="checkbox"/>            | Spain           | <input type="checkbox"/> | Sweden         | <input type="checkbox"/> | United Kingdom | <input type="checkbox"/> |
| Iceland   | <input type="checkbox"/> | Norway   | <input checked="" type="checkbox"/> |                 | <input type="checkbox"/> |                | <input type="checkbox"/> |                | <input type="checkbox"/> |

**2. ACTIVE SUBSTANCE**

|                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1. Common name                                                                                   | Rotenone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.2. EC and/or CAS N°                                                                              | EC no: 650-005-00-2<br>CAS no: 83-79-4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2.3. Molecular and Structural formula (including details on isomeric composition) – molecular mass | <p>Molecular formula: <math>C_{23}H_{22}O_6</math><br/>Molecular mass: 394,45 g/mol</p>  <p>Structural formula:</p>                                                                                                                                                                                                                                                                                                                                                                                               |
| 2.4. Method of manufacture (in brief terms)                                                        | <p>Rotenone is an isoflavonoid occurring in extracts from the roots of certain plants belonging to the Leguminosae family. Plant roots are dried and ground, and a resin containing the active substance is extracted. The rotenone-containing resin is used as a basis for manufacture of piscicidal products. The active substance can be further purified and ground to form a crystalline powder.</p> <p>Rotenone is insoluble in water and for use as a piscicide it is normally formulated as a liquid emulsion in order to allow for rapid and efficient dispersion and improved efficacy.</p> |
| 2.5. Specification of purity in g/kg or g/l as appropriate                                         | <p>Typical purity of rotenone active substance is 995 g/kg or 99.5 % (w/w).<br/>Typical purity of the rotenone-containing resin (cube extract) is 48% (w/w).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.6. Identity of impurities and additives – including stabilisers                                               | <p>Typical composition of the biocidal product for which essential use is claimed is :</p> <p>Active substance: Rotenone – 5,3 %</p> <p>Non-piscicidal resins – 4,7%</p> <p>Solvent: Diethylene-glycol-monoethyl-ether -57,5 %</p> <p>Solvent: 1-methyl-2-pyrrolidone -10,0 %</p> <p>Emulsifier: Fennedefo 99™ (fatty acid esters and polyethylene glycol mix) - 20,0 %</p> <p>Emulsifier: Benzene sulphonic acid - 2,0 %</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.7. Origin of substance (in case of a natural substance)                                                       | <p>Rotenone is derived from the roots of Derris spp., Lonchocarpus spp., and Tephrosia spp.; plants that are most commonly found in South America, Australia and South East Asia, and East Africa.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.8. Physical chemical properties in accordance with Annex IIA, Point III, to Directive 98/8/EC, as appropriate | <p><b>Melting point:</b> 165 °C</p> <p><b>Boiling point:</b> 210 – 220 °C</p> <p><b>Relative density:</b> 1,27 g/cm<sup>3</sup></p> <p><b>Vapour pressure:</b> &gt; 1 mPa (20 °C)</p> <p><b>Henry's law constant:</b> &lt; 0.03 Pa·m<sup>3</sup>·mol<sup>-1</sup></p> <p><b>Appearance:</b> Crystals, colourless, odourless</p> <p><b>Solubility in water:</b> 0,00002 g/100 ml (20 °C)</p> <p><b>Solubility in organic solvents:</b> (20 °C, in 100 ml) Ethylalcohol 0.2g; Carbon tetrachloride 0.6g; Amylacetate 1.6 g; Xylene 3.4 g; Ethylene dichloride 33.0 g; Chloroform 47.2 g; Acetone 6.6 g; Benzene 8.0 g; Chlorobenzene 13.5 g</p> <p><b>Partition coefficient n-octanol / water:</b> 4.10 Log Pow</p> <p><b>Explosive properties:</b> Non-explosive</p> <p><b>Oxidizing properties:</b> Non-oxidizing</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 2.9. A summary or toxicological and ecotoxicological information for the substance                              | <p>The toxicity of rotenone stems from its specific effect on cellular aerobic respiration, blocking mitochondrial electron transport by inhibiting NADH-ubiquinone reductase. This suspends cellular utilisation of oxygen for energy production in the form of nucleoside triphosphates, eventually leading to cardiac and neurological failure.</p> <p>Rotenone is highly toxic to fish due to the rapid uptake of the substance across the gill surface. It is less toxic to aquatic invertebrates and to amphibians and reptiles, whereas waterfowl and other birds as well as mammals are comparably resistance to cutaneous and oral exposure.</p> <p>24-hour LC50 concentrations for rotenone active substance are between 2 and 10 ppb for salmonids, that are among the most susceptible fish species. LC50 for crucian carp (<i>Carassius carassius</i>), goldfish (<i>Carassius auratus</i>) and bullhead catfish (<i>Ictalurus melas</i>) are reported between 33-360 ppb. Oral LD50 for birds were in the range of 1600-3500 mg rotenone/kg, and oral LD50 in the range from 132-1500 mg/kg have been reported for the rat. Estimated oral LD50 for humans is 300-500 mg/kg. Based upon these oral toxicity values, rotenone formulations are placed in Class II (moderately hazardous) or III (slightly hazardous) according to the WHO classification of pesticides.</p> <p>Rotenone is unstable in the presence of light, heat and oxygen and has a short, temperature dependent half-life; down to few hours in summer. Its measurable persistence in natural waters may thus vary from a few days to several weeks dependent on season. The acute toxicity of the active substance is significantly reduced by binding to particulate matter. Rotenone does, however, not persist in sediments and is broken down below detection limits within 14 days at 8°C. This favours the re-population of aquatic species being collaterally damaged by the use of rotenone as a piscicide.</p> |

Only about 25% of absorbed rotenone is found in the fillet of exposed fish with concentrations normally not exceeding 1 ppm, whereas 10 ppm is considered a safe level for human consumption. Observed values suggest that it is physically impossible to ingest poisonous amounts of rotenone by eating rotenone-treated fish. This explains why there have been no reports on toxic events from traditional use of rotenone for catching food fish, or from the use of rotenone-poisoned fish for human consumption following treatment of North American water bodies with rotenone.

An overview and a more comprehensive discussion of the toxicity and environmental risks of rotenone for use as a piscicide was recently published in New Zealand (Ling, 2003).

### 3. AVAILABLE INFORMATION ON THE ESSENTIAL USE

|                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1. Product type and use(s) for which the derogation is required | <p>Essential use is claimed for CFT Legumin™, which contains approximately 5,3% (w/w) of the active substance dissolved in a mixture of diethylene-glycol-monoethyl-ether and 1-methyl-2 pyrrolidone.</p> <p>The product is claimed essential for use as a piscicide for the following purposes:</p> <ul style="list-style-type: none"> <li>a) control and eradication of the Atlantic salmon parasite <i>Gyrodactylus salaris</i> and similar pests</li> <li>b) controlling the spread of invasive aquatic animal species such as the minnow (<i>Phoxinus phoxinus</i>), and</li> <li>c) eradication of exotic species considered to threaten biodiversity and native populations of Norwegian aquatic animal fauna, if introduced.</li> </ul> |
| 3.2. Method(s) of application                                     | <p>The biocide will be dissolved in water through:</p> <ul style="list-style-type: none"> <li>a) application into the water via (manually controlled) pumps and hoses</li> <li>b) dripped onto the water surface from perforated containers ("drip-stations")</li> <li>c) application onto the water surface from a knapsack dispenser.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.3. Number and timing of applications                            | <p>Application of the biocide will normally be as one single treatment per water body, being conducted in one or two steps (dependent on size and complexity of operation) each lasting for one or two consecutive days. Application will be timed in order to maximise treatment effect per liter biocide used, normally co-inciding with periods of low water level and flow. In case of failure to eradicate the target organisms, repeated treatment may become necessary.</p>                                                                                                                                                                                                                                                              |
| 3.4. Classification & Labelling                                   | <p>According to Directive 67/548/EEC:</p> <p>Class of danger: T, N, Xi</p> <p>R phrases: R-25, R-36/37/38, R-50/53</p> <p>S phrases: S-26, S-28, S-38, S-36/37, S-45, S-60, S-61</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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

Voluminous experimental data are available on the acute toxic effects on rotenone on mammals and birds (see tables in Ling, 2003), but likely due to the low concentration (5%) of the active substance there are surprisingly no reports on acute health effects in humans or mammals stemming from its use as a piscicide. Data and reports after intentional or accidental exposure through the use as an insecticide indicate that these preparations may cause skin rash, eye irritation, and/or vomiting. Exposure by inhalation is thereby considered more hazardous than oral or percutaneous exposure. The greatest risk to human health is therefore to manufacturing workers and to operators involved in dispersing the toxicant, for whom the use of protective clothing and/or respirator masks is recommended. Risk mitigation by minimising and avoiding aerosol formation (application underneath the water surface) is further recommended wherever possible.

By its very nature, the use of rotenone as a single-treatment piscicide does not imply frequent or repeated exposure to inhabitants, terrestrial or aquatic fauna, and its short half-life effectively prevents long-term or chronic exposure risks.

3.6. Information on efficacy

The efficacy of rotenone as a piscicide is proven since more than 75 years and is supported by extensive experimental toxicity data (Finlayson et al. 2000, Ling, 2003) The field efficacy of its use in natural waters is highly dependent on the size, complexity and flow of the water body, on the logistics and accurateness of its application, and on the relative sensitivity of the target species relative to non-target fish and invertebrate fauna. In the eradication of the salmon ectoparasite *Gyrodactylus salaris*, rotenone is used to assure a temporal removal of the parasite's host populations in order to achieve complete breakdown of parasite reproduction and death of all parasite stages within few weeks. In the Norwegian eradication programmes for *Gyrodactylus salaris* has until date been successfully eradicated from 15 rivers without re-infection. Eleven rivers are still under post-treatment surveillance to document the absence of the parasite. Only 4 treatments have so far been unsuccessful after the initial attempt, triggering the need for repeated use of the piscicide.

#### 4 - JUSTIFICATION OF THE ESSENTIAL USE

##### 4.1. Significance of the harmful organism(s)

*Gyrodactylus salaris* is a monogenean ectoparasite shown to be highly pathogenic for natural populations of Atlantic salmon (*Salmo salar* L.) parr and smolts (anonymous 2003). By damaging mucus and skin the parasite causes chronic osmotic stress and imbalance, eventually leading to the death of young fish during their freshwater phase, and the prevention of new yearclasses of smolts migrating to sea. Over relatively few years, this will lead to a complete breakdown of the natural reproduction cycle and eventually the extinction of affected salmon populations. *Gyrodactylosis* is a notifiable infectious disease according to Norwegian fish health legislation, and is recognised a significant fish disease by the Office International des Epizooties (OIE) (anonymous, 2002a).

The minnow (*Phoxinus phoxinus*) is considered among the most problematic among invasive species of the Norwegian freshwater fauna (Tømmerås et al. 2003) due to the continuous expansion of its geographical range and in particular its ability to outcompete fry and fingerlings of brown trout (*Salmo trutta*) for food resources and habitat. Studies have shown clear negative effects of the spread of this species to brown trout populations inhabiting Norwegian lakes and rivers (Taugbøl et al. 2002). More than 20 different fish and crustacean species have been characterised as non-native to Norwegian ecosystems, some of which are associated with significant negative effects for biodiversity, recreational fisheries and/or the economic potential of native aquatic wildlife (Tømmerås et al. 2003).

The further spread of the above species or the introduction of further exotic species to the Norwegian fauna may threaten the Norway's fulfilment of international conventions on biodiversity, and will reduce our ability to sustainably manage and preserve the country's natural fish populations.

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

The intended use is essential to continue current pest management programmes against *Gyrodactylus salaris* and *Phoxinus phoxinus* (see below). The quantities needed for conduct of these programmes is highly variable from one year to another, mainly dependent on the actual timing of large river treatments to control *Gyrodactylus salaris*. The estimated maximum quantity needed for essential use in a single year is 2500 kg of rotenone active substance, with an average annual use not exceeding 1500 kg.

#### 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)?

Failure to obtain permission for essential use of rotenone as a piscicide would negatively affect efforts to preserve the health and viability of Norway's natural populations of Atlantic salmon, *Salmo salar* L., that constitute the dominant part of the world's natural populations of this species. It would further hinder Norway's efforts to maintain natural biodiversity and to fulfil its obligations according to international treaties.

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

There is a continued need for rotenone to carry out the Norwegian Government's programmes to control and eradicate the salmon parasite *Gyrodactylus salaris* (anonymous, 2002b; (Parliamentary proposition no 1 2005-2006. Ministry of Environment), and for emergency control of exotic fish diseases of similar severe consequences.

Rotenone used as a piscicide is further deemed an essential tool to control and eradicate invasive and introduced aquatic species, which is a further objective deemed of societal significance (Parliamentary proposition no 1 2005-2006. Ministry of Environment).

## 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.

No other active substances are being used or licensed as a piscicide in the EU. In North America, there has been limited use of antimycin as a piscicide but due to the antibacterial activity of this product, its use and release into the environment is deemed highly undesirable in Norway.

In USA, several rotenone-containing piscicide products have been licensed by the Environmental Protection Agency since the 1950ies, and rotenone has been widely used in US and Canadian fisheries management. In Europe, rotenone has for the last 50 years been used as a piscicide under national legislation (amongst other states in the UK, Norway, Sweden, Finland and Spain). In most cases, use has been sporadically and/or in small quantities.

In the UK and in the USA, rotenone is licensed in numerous formulations and available for use as a general insecticide in gardening and ecological farming. Use of rotenone as an insecticide has until now included its legal use directly onto crop plants and animals.

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

More than 30 substances including toxaphene, diclorvos, endrin, malathion, antimycin, nicotine, and saponins have been used as fish toxicants, but with variable and generally poor success. In most of these cases, the collateral damage to non-target fauna has been significantly greater than seen with rotenone. Further concerns of these alternatives relate to environmental persistence or antimicrobial effects (Ling 2003). As reviewed by Finlayson et al. (2000), there are no realistic alternatives to rotenone use (except complete and prolonged de-watering) for controlling fish populations in natural waters.

Norwegian authorities have commissioned a study to identify alternative methods to control and eradicate *Gyrodactylus salaris* in Atlantic salmon river populations (Skjelstad and Simolin 2001). Numerous medicinal substances have been assessed without presenting a realistic solution to the problem, and current strategies adopted by the Norwegian Directorate of Nature Management and the Ministry for Environment therefore now focus on partial replacement and significant reduction in rotenone use (see below).

## 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

A dossier for evaluation of rotenone for use as a piscicide under Directive 98/8/EC is currently being submitted to the CA of United Kingdom by the trade name holder (VESO, Oslo, Norway) before March 1, 2006.

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

On-going research and development project are currently investigating a partial replacement of rotenone use through long-term treatment of rivers with aluminium sulphate including simultaneous acidification. This method offers the benefit of removing the parasite without killing the host population. So far, the results from two river treatments are promising although complete replacement of rotenone treatments in the control of *Gyrodactylus salaris* is considered unrealistic (Steinkjer 2005).

## 7- OTHER INFORMATION

Research on aluminium sulphate as an alternative to rotenone treatment is believed to significantly reduce the amount of rotenone piscicide needed for to control and eradicate *Gyrodactylus salaris*. Research and development is further on-going to reduce the amount of rotenone needed through the establishment of effective fish barriers, above which natural de-population of susceptible anadromous populations will take place over 5-10 years.

In Norway, use and release of rotenone-containing products into drainage systems and natural waters is covered by national environmental legislation that requires usage of such products to be approved by the environmental protection authorities. This procedure will secure that necessary steps are taken to minimize emissions and their environmental impacts, and human exposure to rotenone.

The short half-life of rotenone, its low toxicity to warm-blooded fauna and humans, the lack of bioaccumulation properties, and the long-term experience of its use without the observation of unacceptable risks or consequences to humans or ecosystems are obviously factors supporting a favourable evaluation relevant to the criteria appendix VI of Directive 98/8/EC.

## References

- Anonymous (2002a). International Aquatic Animal Health Code, fifth edition. Office International des Epizooties, Paris. ISBN: 92-9044-560-2
- Anonymous (2002b). Tiltaksplan for arbeidet med bekjempelse av Gyrodactylus salaris i norske laksevassdrag. Direktoratet for naturforvaltning og Statens dyrehelsetilsyn. [Action plan for control and eradication of Gyrodactylus salaris in Norwegian salmon rivers. Norwegian Directorate for Nature Management and Norwegian Animal Health Authority] September 2002, 19 p.
- Anonymous (2003). Manual of Diagnostic Tests for Aquatic Animals, fourth edition. Office International des Epizooties, Paris. ISBN: 92-9044-563-7.
- Finlayson BJ, Scnick RA, Cailteux RL, deMong L, Horton WD, McClayW, Thompson CW and Tichacek GJ (2000). Rotenone use in fisheries management: Administrative and technical guidelines manual. American Fisheries Society, Bethesda, Maryland.
- Ling N (2002). Rotenone- a review of its toxicity and use for fisheries management. Science for Conservation 211, 40 p. ISBN 0-478-22345-5.
- Skjelstad B and Simolin P (2001). Oppsummering av terapeutika mot lakseparasitten Gyrodactylus salaris, samt prinsipielle problemstillinger knyttet til bruken av dem i behandling av infiserte vassdrag. [Summary of therapeutants against the salmon parasite Gyrodactylus salaris, and principal aspects associated to their potential use in the treatment of infested watercourses]. VESO project report 1476, 31 p. ISBN: 2-91743-09-6.
- Steinkjer J (2005). Behov for bruk av rotenon i framtida [Need for rotenone use in the future]. Memorandum, Norwegian Directorate of Nature Management, November 1, 2005.
- Taugbøl T, Hesthagen T, Museth J, Dervo B and Andersen O (2002). Effekter av ørekyteintroduksjoner og utfiskingstiltak – en vurdering av kunnskapsgrunnlaget. [Effects of minnow introductions and remedial fishing activities – an assessment of the current knowledge basis]. NINA oppdragsmelding 753, 31 p.
- Tømmerås B, Hofsvang T, Jelmert A, Sandlund OT, Sjursen H and Sundheim L (2003). Introduerte arter. Med fokus på problemarter for Norge. [Introduced species; focusing on species posing particular problems for Norway]. NINA Oppdragsmelding 772, 58 p. ISBN: 82-426-1376-1.