Risk Assessment and Risk Management from an Environmental Perspective – PT 19

PT 19 Workshop
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## Active substance approval for PT 19

### 8 approved active substances for PT19 (ECHA homepage, 06/2016)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Date of Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Diethyl-meta-toluamid (DEET)</td>
<td>31.07.2014</td>
</tr>
<tr>
<td>(Z,E)-TDA</td>
<td>31.01.2015</td>
</tr>
<tr>
<td>Nonanoic acid, Pelargonic acid</td>
<td>31.01.2015</td>
</tr>
<tr>
<td>Methyl nonyl ketone</td>
<td>30.04.2016</td>
</tr>
<tr>
<td>cis-Tricos-9-ene (Muscalure)</td>
<td>30.09.2016</td>
</tr>
<tr>
<td>Decanoic acid</td>
<td>31.08.2017</td>
</tr>
<tr>
<td>Ethylbutylacetylaminopropionate (IR3535)</td>
<td>31.10.2017</td>
</tr>
<tr>
<td>Lauric acid</td>
<td>31.10.2017</td>
</tr>
<tr>
<td>Carbon dioxide</td>
<td>under review</td>
</tr>
<tr>
<td>Geraniol</td>
<td>under review</td>
</tr>
<tr>
<td>Lavender, Lavandula hybrida, ext./Lavandin oil</td>
<td>under review</td>
</tr>
<tr>
<td>Margosa extract</td>
<td>under review</td>
</tr>
<tr>
<td>Metofluthrin</td>
<td>under review</td>
</tr>
<tr>
<td>Mixture of cis- and trans-p-menthane-3,8 diol (Citriodiol)</td>
<td>under review</td>
</tr>
<tr>
<td>Pyrethrins and Pyrethroids</td>
<td>under review</td>
</tr>
<tr>
<td>sec-butyl 2-(2-hydroxyethyl)piperidine-1- carboxylate/Icaridine (Icaridine)</td>
<td>under review</td>
</tr>
</tbody>
</table>


Approved biocidal products for PT 19 in DE

15 approved biocidal products for PT19 in DE (BAuA Homepage, 06/2016)
http://www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Biozide/Produkt/Zugelassene-Biozidprodukte.html

All of the so far approved biocidal products in DE contain DEET as active substance

**a. s. content:**
15% up to 50% DEET

**Intended use:**
Ready-to-use repellent solution for skin application (pump spray, roll-on or lotion)

**Target animals:**
Mosquitoes (Culicidae), ticks (Ixodoidea); one biocidal product additionally against sandfly (Phlebotominae)

**Classification/labeling:**
a. s. content ≥ 25% → classification as H412
Exposure assessment PT19

- Until September 2012 no ESD on PT19 was available

- October 2012 – December 2013: Contract between Federal Environment Agency (Germany) UBA and Dr. KnoellConsult GmbH for development of an Emission Scenario Document for repellents and attractants PT19 (FKZ: 22752)

- Finalisation until May 2015 with support by ECHA

Scenarios included in ESD PT19

- Insect repellents applied to human skin and garments

Relevant life-cycle stages to be considered for PT 19 products when assessing environmental emissions due to the use on human skin or clothes:

- Removal through showering and bathing of humans as well as washing of garments
- Release to surface water bodies through swimming
Scenarios included in ESD PT19

- Insect repellents applied on animal skin (mainly for horses, cats and dogs)

- Application of repellents in the environment of humans and animals for the purposes:
  - repellency of arthropods (indoors to favoured places of cats and dogs to repel bloodsucking ectoparasites)
  - prevention of cloth moths entering wardrobes
  - repellency of vertebrates (cats and dogs) by treating objects and places to prevent fouling and other damaging activities

- Insect repellents used for factory-treated textiles
  - release pathways: a) cleaning or washing of treated articles and b) wash-off by rainfall, e.g. leaching of a.s. from treated textile of a camping tent

- Attractants
Risk mitigation measures (RMM)

Assessment Report **DEET** (chapter 3.3 „Elements to be taken into account by Member States when authorising products“)

“Any potential for direct exposure to surface water as a consequence of swimming etc. has not been assessed at the European level.”

-> Level a. s. approval: assessment of **indirect** exposure only (no ESD available)
-> Level product authorisation: direct exposure should also be taken into account

Example for biocidal product authorisation: **Aptonia No Mosquito 30% DEET Spray/Care Plus Anti Insect DEET Spray 30%**

-> Assessment of indirect and direct exposure of surface water/sediment by RefMS NL
-> Result: no unacceptable risks for indirect exposure; **but**  

PEC/PNEC-ratio 1.43 direct exposure for the scenario “high density swimmers in the swimming area”

→ **RMM**: Restriction of the number application “Do not use more than once a day” [SPC 5.1 (6)]
UBA suggested to add an additional RMM to the SPC

„Do not use directly before swimming and bathing in order to protect the aquatic environment„

Justification:

• DEET is classified as H 412 („Harmful to aquatic life with long-lasting effects“) -> classification of b. p. as H412 if a. s. content ≥25%
• Monitoring-data for DEET: detectable in urban and rural areas in concentrations > 520 ng (Wittmer et al., 2014*)
• UBA added this RMM to the SPC of other products during national authorisation and during mutual recognition
• Sustainable use of b.p. – to sensitize the user

But within an informal disagreement with RefMS NL to include the additional RMM in SPC -> DE was not successful

→ Harmonised approach required!

*Wittmer et al., 2014; Aqua & Gas No. 3 (32)
Risk mitigation measures (RMM)

Which measures should be incorporated into the SPC?

Unacceptable risks for surface water/sediment -> RMM
-> where applicable, restriction of use frequency (e.g. „Do not use more than once a day“)
-> additionally: „Do not use directly before swimming and bathing in order to protect the aquatic environment“

No unacceptable risks for surface water/sediment -> constraint
-> „The biocidal product should not be used directly before swimming and bathing in order to protect the aquatic environment“
-> applicable for all PT 19 products used directly on skin (risk-independent, precautionary principle)

Precautionary statements „Avoid release to the environment“ (P273) in dependence of the classification of the biocidal product

Instructions for safe disposal according to national legislation (cf. SPC 5.4) or in dependence of the classification of the biocidal product (P501 „Dispose of contents/container according to local/national law“)
Products for non-professional users: safety data sheet should state the appropriate waste code (as information for transport and trade)
Thank you for your attention!

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