LIFE COMBASE - COMputational tool for the assessment and substitution of Biocidal Active substanceS of Ecotoxicological concern

LIFE15 ENV/ES/416

E-Learning QUIZ & Answers

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LIFE COMBASE is partly funded by the European Commission -Executive Agency for Small and Medium-sized Enterprises- under the European Union's LIFE Fund in the framework of LIFE programme for environmental policy and governance with Grant Agreement number LIFE15 ENV/ES/416.

OUTLINE

1. Module 1: Ecotoxicology. Quiz and answers.
2. Module 2: Computational toxicology. Quiz and answers.
3. Module 3: Biocidal Products Registration. Quiz and answers.
4. Module 4: Good Practices. Quiz and answers.

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1. Module 1: Ecotoxicology. Quiz and answers.

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Quiz 1: You are evaluating the potential risk of a chemical for the freshwater environment. To do this you have conducted 3 short-term bioassays. The results of tests are shown in the next table. To evaluate the risk, please calculate the PNEC for the chemical substance.

Available data	Organism tested	Endpoint	Technical Guideline	Value
L(E)C 50	Invertebrate (*Daphnia magna*)	Immobilization- Short term	OECD 202	10mg/L
L(E)C 50	Algae (*P. subcapitata*)	Growth inhibition Short term	OECD 201	1mg/L
L(E)C 50	Fish (*O. mykiss*)	Mortality -Short term	OECD 203	20mg/L

Quiz 2: After calculating the PNEC, please answer this question: if the concentration of the substance in water (PEC) is 0.05 mg/L, is the risk acceptable?

Quiz3: According the L(E)C 50 shown in the table. Please, classify from higher to lower sensibility to the toxic the 3 species used in the estudy.

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Quiz4: According to the NOEC, LOEC and EC50 definiton. Which of the three options is true?

1. NOEC > LOEC > EC50
2. NOEC < LOEC < EC50
3. NOEC > EC50 < LOEC

Quiz5: We have two compounds, “A” and “B”, the EC50 for the “A” compound is 5 mg/L and the toxicity for the “B” compound is 500 mg/L. What compound is more toxic?

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Answer Q1

Assessment Factor? 1000
PNEC? 1 mg/L / 1000 (AF) = 0.001 mg/L or 1 μg/L

Explanation

We have 3 L(E)C 50 data from three short term bioassays, according the BPR Directive, the AF to be applied is 1000

Answer Q2

If the concentration of the substance in water is 0.05mg/L, the risk is not acceptable.

Explanation

For PNEC, Short-term results L(E)C 50 from three species are available. An assessment factor of **1000** is assigned to the lowest L(E)C50 value of the 3 species. The risk assessment is PEC/PNEC = 0.05 / 0.001 > 1, so is not acceptable

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Answer Q3

Algae (1 mg/L) > *Daphnia magna* (10 mg/L) > fish (20 mg/L)

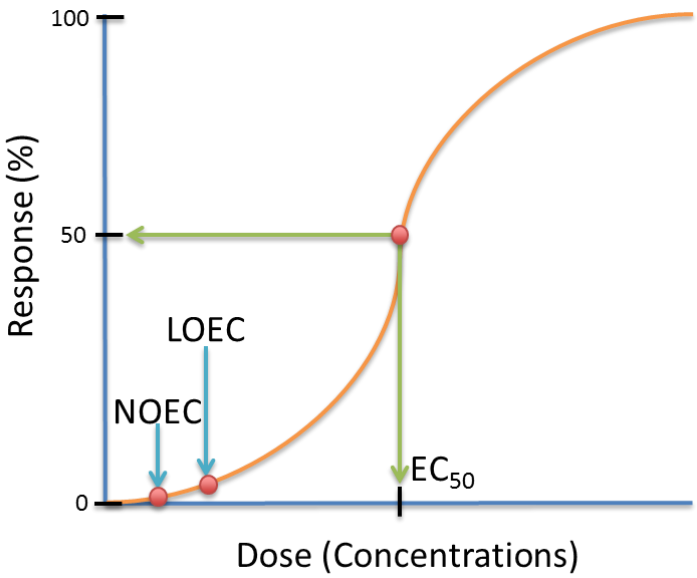
Explanation

The key to answer is the C(E)L 50 definition, that is the concentration needed to kill the 50% of the population exposed to the chemical. In the example 1 mg/L is needed to kill the 50% of algae exposed to the compound. To kill the 50% of daphnids exposed it is needed 10 mg/L and finally, to kill the 50% of fishes exposed it is needed20 mg/L of chemical substance.

Answer Q4

Option 2

Explanation



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Answer Q5

"A" is more toxic than "B"

Explanation

As in the Quiz3, the key rule to answer the question is found in the EC50 definition

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2. Module 2: Computational toxicology. Quiz and answers.

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Quiz 1: In the assessment of the biological activity of a molecule from a toxicological perspective, which are the three possible approaches? Give a brief explanation of each one.

Quiz 2: Numerate three possible ways to represent a chemical formula in order to calculate the molecular descriptors or fragments

Quiz 3: Define the “neighbourhood behaviour” principle

Quiz 4: Which are the differences between read-across and QSAR approaches in chemoinformatics?

Quiz 5: Numerate the main OECD principles determining whether a QSAR model is suitable for regulatory use

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Answer Q1

There are three different approaches:

- *In vivo*: experimentation using the whole living organism
- *In vitro*: experimentation using cell cultures or tissue portions of an organism.
- *In silico*: experimentation based on predictions by computer simulation.

Answer Q2

1. InChI
2. SMILES
3. SDF Format

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Answer Q3

The Read Across computer model is based on the **neighbourhood principle**. These are the main characteristics of the principle:

- Chemicals with common structural features → show similar physicochemical properties, toxicological (human health/ecotoxicity) effects or environmental fate properties.
- Substances sharing structural similarities → grouped in the same chemical category
- Once a group has been established → it is possible to use information from the data rich members to fill data gaps.

Answer Q4

Read-across	QSAR
• A case-to-case basis • Reliability supported by specific explanation • Supporting data needed (generic and/or substance-specific) • Subjective expert assessment	• Pre-built model • Reliability supported by the applicability domain • Supporting examples from training sets • Objective output (though it requires an evaluation by the expert)

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Answer Q5

Principle 1: a defined endpoint. The aim of this principle is to ensure the transparency in the endpoint for being predicted by a given model.

Principle 2: an unambiguous algorithm to ensure the transparency in the description of the model algorithm

Principle 3: a defined domain of applicability to generate reliable predictions

Principle 4: appropriate measures of goodness of fit, robustness and predictability.

Principle 5: a mechanistic interpretation between the descriptors used in the model and the endpoint being predicted.

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3. Module 3: Biocidal Products Registration. Quiz and answers.

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Quiz 1: Would a submission made under the REACH Regulation satisfy the requirements of the BPR?

Quiz 2: Do ecotoxicological and toxicological tests have to comply with the principles of good laboratory practices (GLP)?

Quiz 3: What must any entity do if it needs to perform tests or studies involving the use of animals under the BPR?

Quiz 4: What is the procedure to follow on the approval of a new active substance under the BPR Regulation?

Quiz 5: Provide the maximum approval period for a new active substance, for an active substance that meets the substitution criteria and for an active substance meeting the exclusion criteria.

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Answer Q1:

No, the BPR is a different regulation and a separate application needs to be submitted.

Answer Q2:

According to point 6 of Annexes II and III to the BPR, ecotoxicological and toxicological tests should be performed in compliance with the principles of good laboratory practice or other international standards recognized as being equivalent by the Commission or ECHA. Note that for the time being, no 'other international test methods' within the meaning of point 6 of Annexes II and III to the BPR have been recognized by the Commission or by ECHA.

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Answer Q3:

Any entity intending to perform **tests on vertebrates** is required to first inquire with ECHA whether such tests or studies have already been submitted to a competent authority under the BPR or Directive 98/8/EC (the previous legislation). Such an inquiry is optional in case of **tests not on vertebrates**.

If such tests or studies have been submitted, ECHA will provide the prospective applicant with the contact details of the data submitter. In cases where the data submitter is not entitled to negotiate access to the data, they are required to facilitate the contact between the prospective applicant and the actual data owner.

Where such an inquiry is made, and the studies have been submitted under either the BPR or Directive 98/8/EC, data sharing obligations apply.

If such tests do not exist and such entity would like to initiate them then as laid out in the introduction to Annex III to the BPR "The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out" (emphasis added).

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Answer Q4:

0. Corresponding entity requests new substance authorization to the Member State competent authority.
1. Evaluation of the active substance by a Member State competent authority.
2. The results are submitted to ECHA´s Biocidal products Committee
3. An opinion is prepared within 270 days
4. Decision- making by the European Commission and Member States
5. Approval/rejection of the new active substance

Answer Q5:

Approval for an active substance can be granted for a maximum period of 10 years (renewable).
Approval for an active substance that meets the substitution criteria can be granted for a maximum period of seven years (renewable).
Approval for an active substance that meets the exclusion criteria will not be granted unless the substance meets the derogation conditions of Article 5(2) of the BPR. In such cases, approval may be granted for a maximum period of five years (renewable).

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4. Module 4: Good Practices. Quiz and answers.

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Quiz 1: Define the 4 main biocidal groups and provide two examples of product types (PT) pertaining to each one.

Quiz 2: Which actions would you recommend to promote the sustainable use of biocidal products in general terms, in agreement with the COWI A/S Report from 2009; *Assessment of different options to address risks from the use phase of biocides.*

Quiz 3: Describe the key essentials in an Integrated Pest Management strategy.

Quiz 4: Provide some tips for the mixing/loading step of products under PT18.

Quiz 5: Provide a few examples of the possible sectors of application of biocidal products identified in the Best Practice Module for biocidal products pertaining to PT18.

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Answer Q1

Main Group 1: Disinfectants. Human hygiene and food and feed area
Main Group 2: Preservatives. Film and Wood preservatives
Main Group 3: Pest control. Insecticides, acaricides and products to control other arthropods and rodenticides
Main Group 4: Other biocidal products. Antifouling products and embalming and taxidermist fluids

Answer Q2

- Reduce the quantities to optimal levels
- Reduce hazardousness
- Reduce the releases and exposures by application
- Reduce the long- term releases and exposures during the service of biocide- containing materials and articles
- Prevent the development od resistance

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Answer Q3

1. Inspect to establish the extent and location of the infestation
2. Prescribe the best treatment strategy for the particular situation
3. Communicate to set the right expectations and gain sufficient co- operation
4. Treat using the most effective products in the best and safety ways
5. Follow- up to assess results and re- treat if necessary.

Answer Q4

In general, closed mixing and loading systems are preferred. The American Society for Testing and Materials has recommend a series of features in a well-designed closed system including:

- Design simplicity
- Selection of components resistant to chemical corrosion
- Use of vacuum pumps which are considered to be safer and easier to operate than positive-pressure pumps.

The identification of hazard points and critical parts is recommended. Once identified, an inspection and maintenance program is to be set up.

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Answer Q5

1. Social care sector.
2. Hospitality Industry
3. Housing sector
4. Catering sector

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THANKS FOR YOUR ATTENTION!

QUESTIONS?

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