

## Case 1 DPD+

The purpose of this case is to get some experience in using the DPD+ methodology. You can find the [guidance document for the DPD+-methodology on this platform](http://elearn.moodle2.dk/mod/resource/view.php?id=259) (<http://elearn.moodle2.dk/mod/resource/view.php?id=259>).

Q 1)

Mark the below classification which cannot be handled by the DPD+-methodology and where expert judgement is required:

|            |            |           |
|------------|------------|-----------|
| Xn;R22     | Mut 2; R46 | R42       |
| Xi;R38     | R52/53     | R43       |
| Carc 1;R45 | N;R51/53   | Rep 2;R60 |
| T+;R28     | R67        | C;R35     |

Q 2)

Please tick the critical substance(s) in relation to dermal exposure (by only using the general classification concentration limits):

Mixture A)

- 80 % 2-Methylpyridine  
Classification: R10 Xn;R20/21/22 Xi;R36/37
- 15 % 2,3-Dinitrophenol  
Classification: T;R23/24/25 R33 N;R51/53
- 5 % Hexachlorocyclopentadiene  
Classification: Xn;R22 T;R24 Tx;R26 C;R34 N;R50/53

Mixture B)

- 68 % Propylencarbonate  
Classification: Xi;R36
- 30 % Morpholine  
Classification: R10 Xn;R20/21/22 C;R34
- 2 % Sodium fluoracetate  
Classification: Tx;R26/27/28 N;R50

Mixture C)

- 34 % o-Xylene  
Classification: R10 Xn;R20/21 Xi;R38
- 33 % p-Xylene  
Classification: R10 Xn;R20/21 Xi;R38
- 33 % m-Xylene  
Classification: R10 Xn;R20/21 Xi;R38

Q 3)

Please tick the critical substance(s) in relation to inhalation exposure (by only using the general classification concentration limits):

Mixture A)

89 % n-Propyl Alcohol

Classification: F;R11 Xi;R41 R67

Vapor pressure: 15 Torr

10 % Acetonitrile

Classification: F;R11 Xn;R20/21/22 Xi;R36

Vapor pressure: 89 Torr

1 % Methanol

Classification: F;R11 T;R23/24/25-39/23/24/25

Vapor pressure: 97 Torr

Mixture B)

45 % o-Xylene

Classification: R10 Xn;R20/21 Xi;R38

Vapor pressure: 6,2 Torr

45 % Pyridine

Classification: F;R11 Xn;R20/21/22

Vapor pressure: 18 Torr

10 % Cyclohexane

Classification: F;R11 Xn;R65 Xi;R38 R67 N;R50/53

Vapor pressure: 78 Torr

## Case 2 Preparation of exposure scenario for a cleaning agent

The composition of a professional cleaning agent “Multizymes” is as shown in the below table.

Table 0.1 Composition of Multizymes

| CAS-RN    | REACH                 | Name            | Concentration in product (wt%) (W <sub>i</sub> ) |
|-----------|-----------------------|-----------------|--|
| 532-32-1  | 01-2119460683-35-xxxx | Sodium benzoate | 0.5  |
| 67-63-1   | 00-2119455854-00-xxxx | 2-propanol      | 12.5   |
| 9000-90-2 | 01-2119938627-26-xxxx | Amylase         | 2  |
| 9014-01-1 | 01-2119480434-38-xxxx | Subtilisin      | 4  |

All substances are REACH registered and the formulator has received exposure scenarios for all substances.

The formulator wants to make a flexible, consolidated exposure scenario for the product. Therefore, he also wants to include several PROCs covering the same activity, as he knows that his customers do not handle the product in the precise same way.

The formulator has received exposure scenarios for all substances in his product – both covering his own use and his customers use.

Table 0.2 gives an overview of the customer uses of the product.

Table 0.3 gives an overview of the information of the received ES.

Table 0.4 gives an overview of the substance data.

Exercise 1: Prepare a flexible, consolidated ES (manually) for the end-use, assuming that no scaling can be used.

a) Identify the critical components for each exposure route

b) for each exposure route, collect the relevant operational conditions (OP) and relevant Risk Management Measures (RMMs) from the ES for the critical components

c) select the most conservative RMMs and OPs (from above) and prepare the final list of RMMs and OPs

Exercise 2: Prepare a flexible, consolidated ES (using ES-Creator) for the end-use, assuming that scaling using the exposure models is allowed. *Note that the substances and their properties already are defined in ES-Creator.*

Table 0.2 End use of Multizymes

| Life cycle stage<br>DoU | Process categories   | Amount        | Conc. (%)                | Duration per day | Outdoor | Indoor with LEV | Indoor without LEV | Respiratory Protection | Eye protection (goggles) | Protection of hands (gloves) |
|-------------------------|--|---------------|--------------------------|------------------|---------|-----------------|--------------------|------------------------|--------------------------|------------------------------|
| End use<br>PC35         | Activity   | <2000 kg/year | Concentration of product |                  |         |                 |                    |                        |                          |                              |
| ERC 4<br>SU 20          | Transfer of industrial detergent, maintenance or disinfectant (charging/discharging) to a dedicated cleaning equipment (machine/vessel)        | PROC8a        | 100                      | 60               | No      | No              | Yes                | No                     | Yes                      | Yes                          |
|                         | Transfer of industrial detergent, maintenance or disinfectant (charging/discharging) to a not-dedicated cleaning equipment (bucket or similar) | PROC8b        | 100                      | 60               | No      | No              | Yes                | No                     | Yes                      | Yes                          |
|                         | Dilution of cleaning agent   | PROC5         | 10                       | 15               | No      | No              | Yes                | No                     | Yes                      | Yes                          |
|                         | Using a diluted industrial cleaning solution in a closed cleaning equipment  | PROC1         | 10                       | 480              | No      | No              | Yes                | No                     | No                       | No                           |
|                         | Using a diluted industrial cleaning solution in a semi closed cleaning equipment   | PROC2         | 10                       | 480              | No      | No              | Yes                | No                     | No                       | No                           |
|                         | Using the diluted product in a dedicated equipment; opportunity for exposure arises  | PROC4         | 10                       | 480              | Yes     | No              | Yes                | No                     | No                       | No                           |
|                         | Pressure spraying of a diluted industrial cleaning product.  | PROC 11       | 10                       | 480              | Yes     | No              | Yes                | Yes                    | Yes                      | Yes                          |
|                         | Brushing an industrial cleaning solution   | PROC10        | 100                      | 480              | Yes     | No              | Yes                | No                     | Yes                      | Yes                          |
|                         | Brushing a diluted cleaning or product (after spraying)  | PROC10        | 10                       | 480              | Yes     | No              | Yes                | No                     | Yes                      | Yes                          |
|                         | Treatment of articles by dipping or pouring with product   | PROC13        | 100                      | 220              | No      | Yes             | No                 | No                     | Yes                      | Yes                          |
|                         | Quality control of products  | PROC15        | 100                      | 60               | No      | No              | Yes                | No                     | Yes                      | Yes                          |

Table 0.3 Overview of received ES for the ingredients. Life cycle stage: End-use. SU: SU 20. ERC: ERC 4. PC: PC35

| Activity   | ERC              | sodium benzoate | Yearly amount                |              |     |                        |        |         | Yearly amount                |              |     |                        |        | Yearly amount                |              |     |                        |        |
|--|------------------|-----------------|------------------------------|--------------|-----|------------------------|--------|---------|------------------------------|--------------|-----|------------------------|--------|------------------------------|--------------|-----|------------------------|--------|
|  |                  |                 | 2-propanol                   |              |     |                        |        |         | Amylase                      |              |     |                        |        | Subtilisin                   |              |     |                        |        |
| Activity   | Process category | sodium benzoate | Max conc. Of substance (wt%) | Max duration | LEV | Respiratory Protection | Gloves | Goggles | Max conc. Of substance (wt%) | Max duration | LEV | Respiratory Protection | Gloves | Max conc. Of substance (wt%) | Max duration | LEV | Respiratory Protection | Gloves |
| Industrial end-use as cleaning agents  | ERC 4            | -               | <b>&lt;10,000 kg/year</b>    |              |     |                        |        |         | <b>&lt;100 kg/year</b>       |              |     |                        |        | <b>&lt;10 kg/year</b>        |              |     |                        |        |
| Transfer of industrial detergent, maintenance or disinfectant (charging/discharging) to a dedicated cleaning equipment | PROC8a           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Transfer of industrial detergent, maintenance or disinfectant (charging/discharging) to a dedicated cleaning equipment | PROC8b           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Dilution of cleaning agent   | PROC5            |                 | 100                          | >4 hr/d      | No  | No                     | No     | No      | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Using a diluted industrial cleaning solution in a closed cleaning equipment  | PROC1            | -               | 100                          | >4 hr/d      | No  | No                     | No     | No      | 5                            | >4 hr/d      | No  | No                     | No     | 5                            | >4 hr/d      | No  | No                     | No     |
| Using a diluted industrial cleaning solution in a semi closed cleaning equipment                                       | PROC2            | -               | 100                          | >4 hr/d      | No  | No                     | No     | No      | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Using the diluted product in a dedicated equipment; opportunity for exposure arises                                    | PROC4            | -               | 100                          | >4 hr/d      | No  | No                     | No     | No      | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Spraying of cleaning product.  | PROC11           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | <15 min/d    | No  | Half-mask              | Yes    | 5                            | <15 min/d    | No  | Half-mask              | Yes    |

| Activity   | ERC              | sodium benzoate | Yearly amount                |              |     |                        |        |         | Yearly amount                |              |     |                        |        | Yearly amount                |              |     |                        |        |
|--|------------------|-----------------|------------------------------|--------------|-----|------------------------|--------|---------|------------------------------|--------------|-----|------------------------|--------|------------------------------|--------------|-----|------------------------|--------|
|  |                  |                 | 2-propanol                   |              |     |                        |        |         | Amylase                      |              |     |                        |        | Subtilisin                   |              |     |                        |        |
| Industrial end-use as cleaning agents                          | ERC 4            | -               | <b>&lt;10,000 kg/year</b>    |              |     |                        |        |         | <b>&lt;100 kg/year</b>       |              |     |                        |        | <b>&lt;10 kg/year</b>        |              |     |                        |        |
| Activity   | Process category | sodium benzoate | Max conc. Of substance (wt%) | Max duration | LEV | Respiratory Protection | Gloves | Goggles | Max conc. Of substance (wt%) | Max duration | LEV | Respiratory Protection | Gloves | Max conc. Of substance (wt%) | Max duration | LEV | Respiratory Protection | Gloves |
|  |                  |                 |                              |              |     |                        |        |         |                              |              |     |                        |        |                              |              |     |                        |        |
| Brushing an industrial cleaning solution                       | PROC10           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Brushing a <u>diluted</u> cleaning or product (after spraying) | PROC10           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | >4 hr/d      | No  | No                     | Yes    | 5                            | >4 hr/d      | No  | No                     | Yes    |
| Treatment of articles by dipping or pouring with product       | PROC13           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | >4 hr/d      | Yes | No                     | Yes    | 5                            | >4 hr/d      | Yes | No                     | Yes    |
| Quality control of products                                    | PROC15           | -               | 100                          | >4 hr/d      | No  | No                     | No     | Yes     | 5                            | <4 hr/d      | Yes | No                     | Yes    | 5                            | <4 hr/d      | Yes | No                     | Yes    |

Table 0.4 Overview of substance data.

| CAS_RN    | EINECS    | Name                      | logKow | Physical state       | Psat (Pa) | Psat_temp (°C) | Sw (mg/L) | Sw_temp (°C) | Biodegradability | Mw    | Melting_point (°C) | Boiling_point (°C) | Classification (67/548/EEC)                    | CLP Classification (EC 1272/2008)  |
|-----------|-----------|---------------------------|--------|----------------------|-----------|----------------|-----------|--------------|------------------|-------|--------------------|--------------------|--|--|
| 532-32-1  | 208-534-8 | Benzoic acid, sodium salt | 1.88   | Slightly dusty solid | 4.90E-07  | 25             | 556000    | 25           | RB               | 144.1 | 436                | 450                | Xi; R36  | Eye Irrit. 2A H319   |
| 67-63-0   | 200-661-7 | propan-2-ol               | 0.05   | Liquid               | 6050      | 25             | 1000000   | 25           | RB               | 60.1  | -89.5              | 82.3               | F; R11 Xi; R36 R67                             | Flam. Liquid 2 H225; Eye Irrit. 2 H319; STOT Single Exp. 3 H336  |
| 9000-90-2 | 232-565-6 | Amylase, $\alpha$ -       | -2.95  | Slightly dusty solid | 1.00E-20  | 25             | 1000000   | 25           | RB               | 1000  | 50                 | 500                | R42  | Resp. Sens. 1 H334   |
| 9014-01-1 | 232-752-2 | Subtilisin                | -3.1   | Slightly dusty solid | 1.00E-20  | 25             | 1000000   | 25           | RB               | 1000  | 50                 | 500                | Xn; R22 Xi; R36/37/38 R42 N; R50 <sup>1)</sup> | Acute Tox. 4 H302; Skin Irrit. 2 H315; Eye Irrit. 2 H319; Resp. Sens. 1 H334; Aquatic Acute 1 H400 <sup>1)</sup> |

RB: Readily biodegradable

1): Has another classification in CLP annex VI (table 3.1, 3.2)