

# PRODUCT DEFINITION

## Summary

pCure is a collection of household products that can remove selected environmentally hazardous pharmaceutical residues. The active ingredient in the products are enzymes. As the products are installed and used in the toilets, enzymes are released into the sewage system with each toilet flush.

## About the product definition

- Aims to simplify the customer's understanding of the product effects and functions.
- Contains the fundamental product claims.
- Serves as the foundation of the product message used in communications (packaging, media, websites, etc.).
- The product definition and verification process are built up according to the requirements of ETV/ISO14034.
- The analyses performed during the verification process are established by following the requirements of ISO 17025.
- The valid version of the product definition is published online at <https://help-pcure.se>

## Definitions

- pCure: All valid product versions, i.e. pCure Home, pCure Business and pCure Healthcare.
- Product(s): All valid pCure versions, see above.
- Enzyme(s) Enzymes are proteins that can catalyse (i.e. increase the speed) chemical reactions.
- Enzyme blend(s): Mixture of different enzyme types and/or preparations.
- Substance(s): Refers to one or more pharmaceutical residues that pCure intends to have effect towards.
- Pharmaceutical residue: Refers to one or more substances that are excreted in urine or stool from the consumption of medicine, which are difficult to remove.
- Effect: Removal of substance over time at defined conditions.
- Parameters: Parameters for evaluating the product performance and effect.

## Claim 1: " The product releases active ingredient by dissolution"

### Explanation:

- The products have a block mass formulation that contains enzymes as active ingredients.
- An installed product will dissolve and release block mass, and thereby enzymes, as the toilet is flushed.
- The release of block mass is not constant and is related to the average dissolving behaviour of the product over its lifetime
- The average dissolving behaviour of the product is determined as a mean value of dissolved block mass during its lifetime.
- The average dissolving behaviour of the products is regularly tested according to a standard dissolving process on various common toilet models applied in the EU.
- The release mechanism is also dependent on flushing frequency, the placement of the block in the toilet, toilet model, or similar.
- The other ingredients of the products have been selected with consideration for the environment.

### Parameters:

- |                                |                                                  |
|--------------------------------|--------------------------------------------------|
| • Dissolving behaviour         | Average number of flushes to dissolve block-mass |
| • Level of enzyme in the block | % or g                                           |
| • Product durability           | time (months)                                    |

### Documentation (Examples):

- Method description: Standard dissolving Test
- Report(s): Dissolving behaviour
- Product specification

## Claim 2: "The product have effect on selected environmentally hazardous pharmaceutical compounds"

### Explanation:

- The qualitative effects of the products towards a substance is measured as removal of substance over time.
- The qualitative effects of the enzymes used in the products to remove a substance are analysed in real environments, simulated real environments and/or in laboratory environments.
- The results from the qualitative analysis is showing typical/average values of the product in the defined environment.
- Altering parameters from the standardised method of analysis affects the performance of the product.
- The enzymes applied in the products can show effect on several selected pharmaceutical compounds.
- The enzymes applied in the products can show effect on a broad selection of different environmentally hazardous pharmaceutical compounds secreted by humans through urine or stool.
- The selection of environmentally hazardous pharmaceutical compounds to remove is made by studying the environmental impact of pharmaceutical compounds.
- The products might remove other pharmaceutical compounds than those that the products have been verified towards.
- Qualitative and quantitative analyses are regularly performed to provide the user with updated product information.

### Parameters:

- |                           |                                                                    |
|---------------------------|--------------------------------------------------------------------|
| • Analytical methods      | According to internal or third party selected method (HPLC + LCMS) |
| • Temperature             | °C                                                                 |
| • pH                      | pH                                                                 |
| • Time                    | h                                                                  |
| • pCure concentration     | mg/L                                                               |
| • Substrate concentration | ng/L or µg/L                                                       |
| • Reaction media          | Standard buffer solution                                           |

### Documentation (Examples):

- Method descriptions for Qualitative analysis of product effect
- Test Report(s): The products effect on substances
- List: Pharmaceutical residues on which pCure has verified effect
- List: Pharmaceutical residues which is considered being of high environmental concern.

### Claim 3: "The product have effect on selected pharmaceutical compounds in the sewage systems"

#### Explanation:

- The quantitative effect of the products towards a substance is measured as removal of substance over time.
- The total product effect of the products should be measured during the time required for the product to be flushed through the toilet and to the nearby municipal sewers.
- The quantitative effects of the enzymes used in the products to remove a substance are analysed in real environments, simulated real environments and/or in laboratory environments.
- The effect of the products is depending on the physical parameters explained in claim 1, the content of pharmaceutical compounds in the sewage water, the sewage water conditions and different sewage infrastructures.
- Altering the parameters in the standardised method of analysis will affect the result of the analysis.
- The enzymes applied in the products can show effect on a broad selection of different environmentally hazardous pharmaceutical compounds secreted by humans through urine or stool.
- The enzymes used in the products remains active towards pharmaceutical compounds until they are inhibited, unfolded or degraded in the sewage system.
- The products might remove other pharmaceutical compounds than those that the products have been verified towards.
- Qualitative and quantitative analyses are regularly performed to provide the user with updated product information

#### Parameters:

- |                           |                                                                    |
|---------------------------|--------------------------------------------------------------------|
| • Analytical methods      | According to internal or third party selected method (HPLC + LCMS) |
| • Reaction media          | Standard solution                                                  |
| • Temperature             | °C                                                                 |
| • pH                      | pH                                                                 |
| • Time                    | h                                                                  |
| • pCure concentration     | mg/L                                                               |
| • Substrate concentration | ng/L or µg/L                                                       |

#### Documentation (Examples):

- Method descriptions for Quantitative analysis of product effect
- Test Report(s): The products effect on substances
- List: Pharmaceutical residues on which pCure has verified effect
- List: Pharmaceutical residues which is considered being of high environmental concern.