

# PRODUCT DEFINITION

## DESCRIPTION & CLAIMS

### GENERAL PRODUCT DESCRIPTION

pCure is a collection of household products that have an effect on selected pharmaceutical residues. The active ingredient in the products is enzymes. During normal product usage, enzymes are released into the connected sewage water system. In the sewage water, the enzymes act on target pharmaceutical residues.

### LIST OF CLAIMS

1. The product releases active ingredients by dissolution
2. The enzymes in the product has effect on selected pharmaceutical compounds
3. The product has effect on selected pharmaceutical compounds in sewage water

# Introduction

## About the product definition

- Aims at simplifying the customer's understanding of the product, its function and effects.
- Contains the fundamental product claims and relevant parameters
- The product definition and its verification process are built up according to the requirements of ISO 14034/ETV.
- The analyses performed during the verification process are established both internally and by accredited third party laboratories according to the requirements of ISO 17025.
- Serves as the foundation of the product message used in communications (packaging, media, websites, etc.).
- The valid version of the product definition is published online at [pCure Labs](#)

## Definitions

pCure:	All valid product versions, i.e. pCure Home, pCure Business and pCure Healthcare or other.
Product(s):	All valid pCure product versions, see above.
Enzyme(s)	Enzymes are proteins that can catalyse (i.e. increase the speed of) chemical reactions.
Enzyme blend(s):	Mixture of different enzyme types and/or preparations.
Compound(s):	Refers to one or more targeted pharmaceutical residues that pCure has effect towards.
Pharmaceutical residue:	Refers to one or more compounds that are excreted in urine or stool from the consumption of medicine, which are difficult to remove.
Effect:	Removal of one or several compounds over time at defined conditions.
Parameters:	Applied conditions used to evaluate the product performance and effect.
Testing environment:	Applied conditions considering relevant aspects of the product in controlled or real environments. This means that the product is analysed according to its product definition, i.e. the average dissolving behaviour is analysed based on normal product use and the effect towards the targeted pharmaceutical residues in controlled or real sewage water is statistically verified.

# Claim 1: The product releases active ingredients by dissolution

## Description

- The products have a block mass formulation that contains an enzyme mixture as an active ingredient.
- An installed product will dissolve and release block mass during normal usage.
- The release of block mass releases an enzyme mixture into the sewage water.
- 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 a variety of common toilet models.
- The average dissolving behaviour is tested towards a defined product usage behaviour.
- The release mechanism is dependent on; flushing frequency, the placement of the block in the toilet, toilet model and current block mass.
- The block mass ingredients have been carefully selected to be environmentally friendly.

## Parameters

Dissolving behaviour:	Average number of flushes to dissolve entire block mass
Enzyme blend content:	% or g

## Documentation

Analytical Procedure:	pCure Standard dissolving test
Report:	Average dissolving behaviour
Specification:	Product specification

# Claim 2: The enzymes in the product has effect on selected pharmaceutical compounds

## Description

- The product effect towards compounds in a controlled environment is measured as removal of compound over time.
- The product effect towards a targeted compound is analysed in various testing environments, including both defined conditions and sewage water.
- The product effect and performance may vary from those published if the product is analysed using other parameters than those defined in the standardized protocols and analytical methods.
- The selection of environmentally hazardous compounds to remove is made by studying the environmental impact of the compound.
- No product effect is claimed towards a compound if the effect has not been verified according to an approved verification process.
- The products might remove other pharmaceutical compounds than those that the product has been verified towards.

## Parameters

Analytical methods:	Internally or third-party analysis method (HPLC/LCMS)
Temperature:	degree, Celsius [°C]
pH:	pH
Time:	Time [h]
Enzyme mixture concentration:	milligram per Litre [mg/mL]
Substrate concentration:	micromolar [µM]
Reaction medium:	Standard buffer solutions

## Documentation

Verification statement:	pCure effect towards "targeted compound"
Verification report:	Verified effect of pCure effect towards "targeted compound"
Methods:	IM-201

# Claim 3: The product has effect on selected pharmaceutical compounds in sewage water

## Description

- The product effect towards a compound is analysed as removal of the compound at a certain time.
- The product effect towards a targeted compound is analysed in sewage water.
- The enzymes released by product dissolution can act on the targeted pharmaceutical residues until they are inhibited, unfolded or degraded.
- The product effect may vary between blocks and user conditions due to the physical product parameters explained in claim 1.
- The product effect is affected by the content of pharmaceutical compounds in the sewage water, the physical and chemical conditions of the sewage water and sewage infrastructure.
- The product effect and performance may vary from those published if the product is analysed using other parameters than those defined in the standardized protocols and analytical methods.
- The product may remove other compounds than those the product has been verified towards.
- Product effect is only claimed towards a compound if the effect has been verified according to an approved verification process.
- Product effect is claimed as a general effect (not specific removal) towards the verified pharmaceutical residue due to the varying conditions affecting the sewage water parameters explained within this claim.

## Parameters

Analytical methods:	Accredited methods (ISO 17025)
Temperature:	degree, Celsius [°C]
pH:	pH
Time:	Time [h]
pCure concentration:	milligram per Litre [mg/L]
Substrate concentration:	nanogram per Litre or microgram per Litre [ng/L] or [µg/L]
Reaction media:	Sampled or buffered sewage water

## Documentation

Verification statement:	pCure effect towards "targeted compound"
Verification report:	Verified effect of pCure effect towards "targeted compound"
Methods:	IM-101, EPA 1694, EPA 539