GARD®potency

Skin sensitizing potency classification according to GHS/CLP

GARDpotency is an *in vitro* add-on test to GARDskin for potency classification according to GHS/CLP.

The assay can subcategorize sensitizers that have been identified by GARDskin (OECD TG 442E) into strong sensitizers (1A) or weak sensitizers (1B).

GARDpotency is included in the OECD Test Guideline Program (TGP 4.106).

Already, GARDpotency results can be used as weight-of-evidence in REACH dossiers for sub-categorization of confirmed skin sensitizers into 1A or 1B according to the GHS/CLP system.

Strong or weak sensitizers?

Features and Benefits

Test system
- Human dendritic-like cell line: SenzaCell™.

Solvent
- Standard: DMSO and H_2O.
- Other available solvents: Acetone, DMF, Isopropanol, Ethanol, Glycerol, Olive oil, Sesame oil.

What it measures
- Gene expression profile of 51 genomic biomarkers.

Readout
- 1A (strong sensitizer) or 1B (weak sensitizer).

High performance
- 88% accuracy for sub-categorization of sensitizers into 1A or 1B.*

Short turnaround time
- 4-6 weeks for standard studies.

Low sample requirement
- 0.5g (solid) or 1ml (liquid).

Compliance
- GARDpotency is included in the OECD Test Guideline Program (TGP 4.106). The ESAC considers that GARDpotency is a functional and valid test method ready for use in industrial screening applications.
- Accepted as weight-of-evidence in REACH dossiers for sub-categorization of confirmed skin sensitizers into 1A or 1B according to theGHS/CLP system.
- GLP or non-GLP.

How GARD® works

GARDpotency is an add-on test to GARDskin. They are performed in a tiered approach for GHS/CLP potency classification.

In the first tier, a test sample is classified by GARDskin as either skin sensitizer or non-sensitizer. If the test sample is classified as a skin sensitizer, it then can be further classified by GARDpotency in the second tier testing.

As a result, the test sample can be sub-categorized as 1A (strong) or 1B (weak) skin sensitizer according to the GHS/CLP system.

All the GARD assays are based on the same technology platform. Read more about the GARD technology platform and assay development principles on www.senzagen.com/science.

Validation study

Method

GARDpotency was performed at three independent laboratories in compliance with the OECD guideline.

The study used a tiered approach, combining GARDskin and GARDpotency for complete hazard identification and potency classification of chemicals.

In the first tier, 28 test substances were tested blindly using GARDskin, 18 of which were classified as sensitizers.

In the second tier, classified sensitizers were then sub-classified by GARDpotency into 1A (strong) or 1B (weak) sensitizers.

Results

The study results are presented in Figure 1, showing a predictive accuracy of 88% for GARDpotency to sub-categorize sensitizers as strong or weak sensitizers.

The overall predictive accuracy is 86% for the tiered approach, classifying the test substances into three categories: strong, weak or non-sensitizers.*

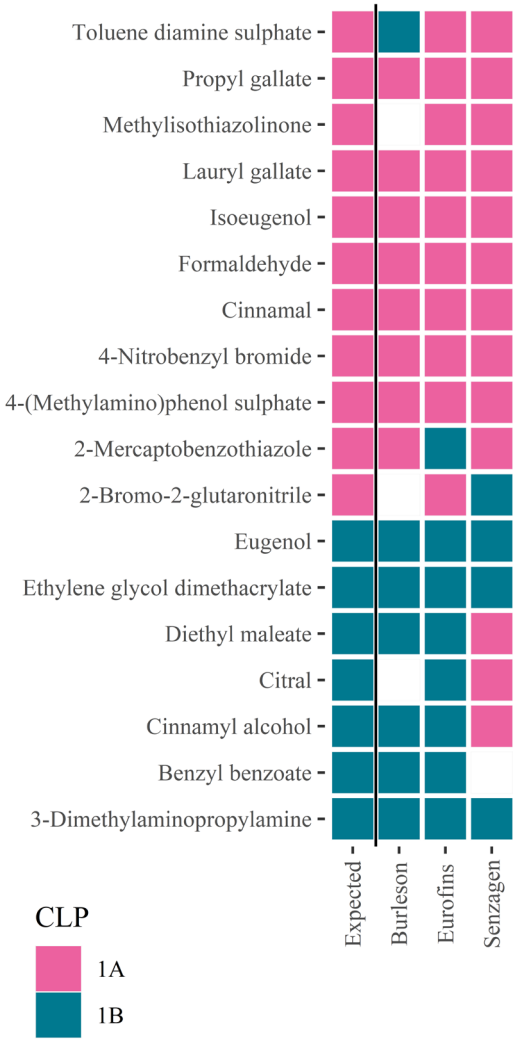

Figure 1. The GARDpotency validation study results from three independent laboratories.

GLP compliant laboratories

SenzaGen's laboratory in Lund is accredited by the Swedish national accreditation body, SWEDAC, for the conduct of *in vitro* toxicity studies with cell systems in compliance with Good Laboratory Practice (GLP).

GARD is also available at selected CRO partners in compliance with GLP.

*Gradin et al. The GARDpotency assay for potency-associated subclassification of chemical skin sensitizers – Rationale, method development and ring trial results of predictive performance and reproducibility. Toxicological Sciences 2020.