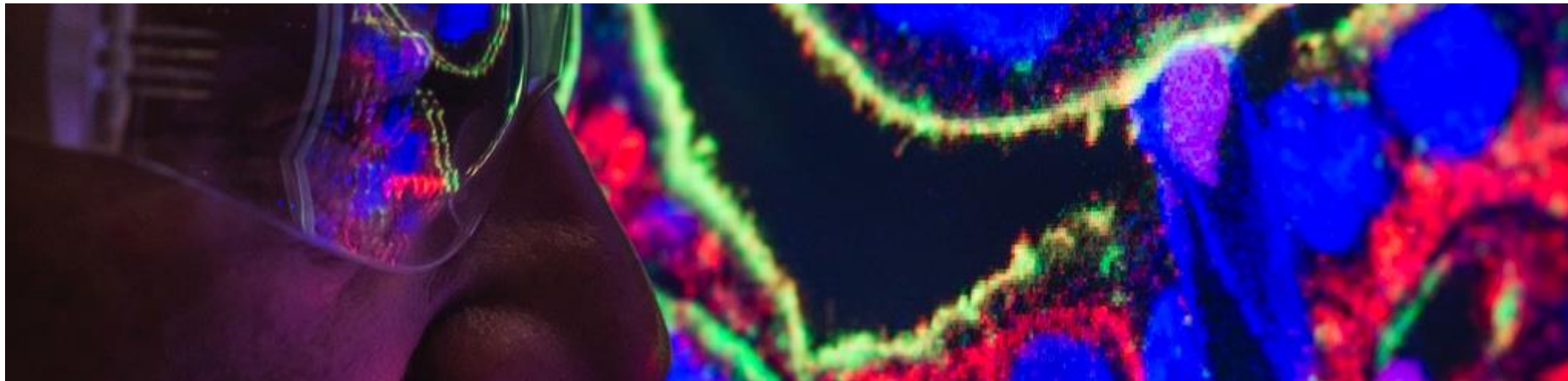


Sampling and Interpretation of Surface Measurements for Chemical Exposure Risk Assessment

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Background

Occupational Exposure Limits for inhaled chemicals
- long experience and well established methods

Skin cases reported despite well below limits in air

No generally accepted concept for defining surface limits for chemical exposure

Local initiatives triggered a company approach



Introduction

Surface Guidance Values

- A concept for **interpretation of surface** sample
- Developed to **assist chemical health risk assessments**
- Should be used as an **indicator** of significant skin **exposure**



How consider skin absorption?

Monitoring?

Estimating?

Using *in silico* models?



Estimate skin absorption

Assumptions and prerequisites

Estimate skin absorption require assumptions difficult to obtain:

Factors of important for skin absorption

- E.g. temperature, humidity, type of skin

Factors from the exposure situation

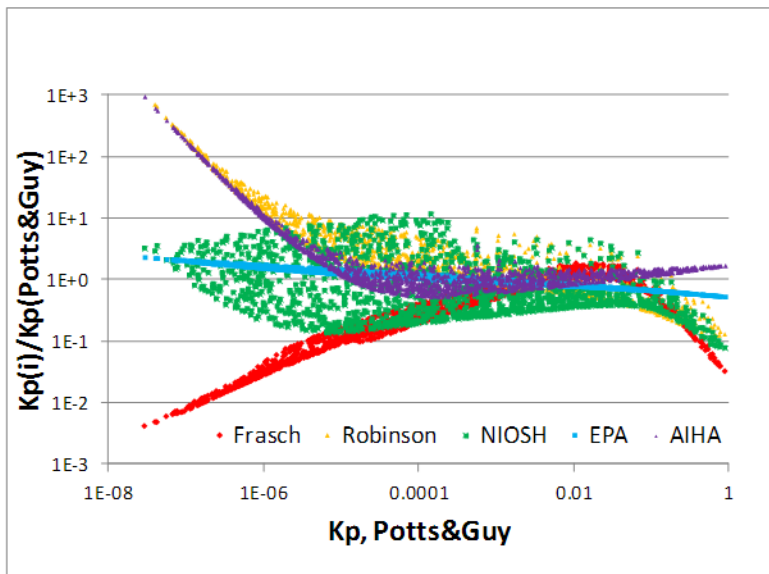
- E.g. exposed skin area, exposure duration, frequency, transfer of chemical from contaminated area to the skin



Skin permeation *in silico* models

A comparison

Skin permeation coefficient (Kp) estimated using 1560 random values (molecular weight: 20 – 799, logKow: -1 –5)



Skin permeation models

A comparison

Max differences between all models = $\frac{\text{Max } k_{p_n}}{\text{Min } k_{p_n}}$

- 80% differ > 3 times
- 64% differ >10 times
- 30% differ >100 times

No agreement between the models

No indication that any model is worse or better

Are in silico predictions useful at all?



Surface Guidance Values

Assumptions and prerequisites

Surfaces expected
to be clean:
SGV = LOQ



Production areas:

SGV = 10% of ADI on 100cm²

ADIs based on our internal OELs

- 100% transfer from surface to skin
- 100% uptake through skin
- 100 cm² representing the area of a palm
- 10% of systemic dose from skin absorption allowed



Sampling and Interpretation of surface measurements

Interpretation of results in production facilities

	Green	Amber	Red
Amount on a surface area of 100cm ²	< 50% of SGV	50 - <100% of SGV	At or above the SGV
Interpretation	May be regarded as acceptable level	Consider the potential skin exposure and transfer of API contaminants	Risk of significant skin exposure and a risk of spread of API contamination to other facilities via hands, shoes and equipment
Action	No actions generally required	Review the need for implementing additional control measures	Implement additional control measures



Surface Guidance Values

Experiences so far...

- Well received in our manufacturing facilities
- A supplement to air monitoring where skin exposure significantly contribute to the total exposure potential
- Used as a tool to identify
 - areas for improvements
 - to ensure appropriate controls are in place
- Support our vision of a PPE free work environment



Many thanks!

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