Creation of a Curated Database of Skin Sensitizers Released from Medical Device Materials

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What are the goals of the project?

1) Create a curated database of device-related skin sensitizers
2) Weight of Evidence (WoE) in directing future studies
3) Evaluate the reliability of prediction models

Why is this work important?

Regulatory

- Development of a proposed skin sensitization IATA for compounds extracted from medical devices (under development by a taskforce of ISO/TC 194 WG11)

Why is this work important?

Biological evaluation of medical devices — Requirements for interlaboratory studies to demonstrate the applicability of validated in vitro methods to assess the skin sensitization of medical devices

Évaluation biologique des dispositifs médicaux — Guide pour les études interlaboratoires visant à démontrer l'applicabilité des méthodes in-vitro validées pour évaluer la sensibilisation cutanée des dispositifs médicaux

ISO

Reference number
ISO/TS 11796:2023(E)

ISO/TS 11796

To qualify the in vitro methods for regulatory use, it is necessary to develop a curated database that is fit for purpose and accurately represents the chemical and biological space of sensitizers released from device materials.

ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

GUIDELINE FOR EXTRACTABLES AND LEACHABLES
Q3E

Draft version

Endorsed on 01 August 2025

Currently under public consultation

Data to be Evaluated and Incorporated into the Safety Assessment

Sensitization Potential/Local Irritation

Relevant available clinical and non-clinical data (supplemented with in silico evaluation, if justified) should be summarized.

Why is this work important?

Regulatory

- Development of a proposed skin sensitization IATA for compounds extracted from medical devices (under development by a taskforce of ISO/TC 194 WG11)
- Qualification of NAMs within a defined context of use (ISO WG8 Round Robin activity and ISO TS
- Safety assessment of compounds released from pharmaceutical packaging (ICH Q3E Draft August 1, 2025)

Clinical

- **A curated list of device-associated skin sensitizers can serve as a resource for dermatologists to identify the most common skin sensitizers released from devices.**

Why is this work important?

A list of skin sensitizer from medical device will help both the manufacturer to improve their products and patients to expect fewer undesired effects while using

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Medical Devices: Adverse Events, the Skin, and Real-World Data

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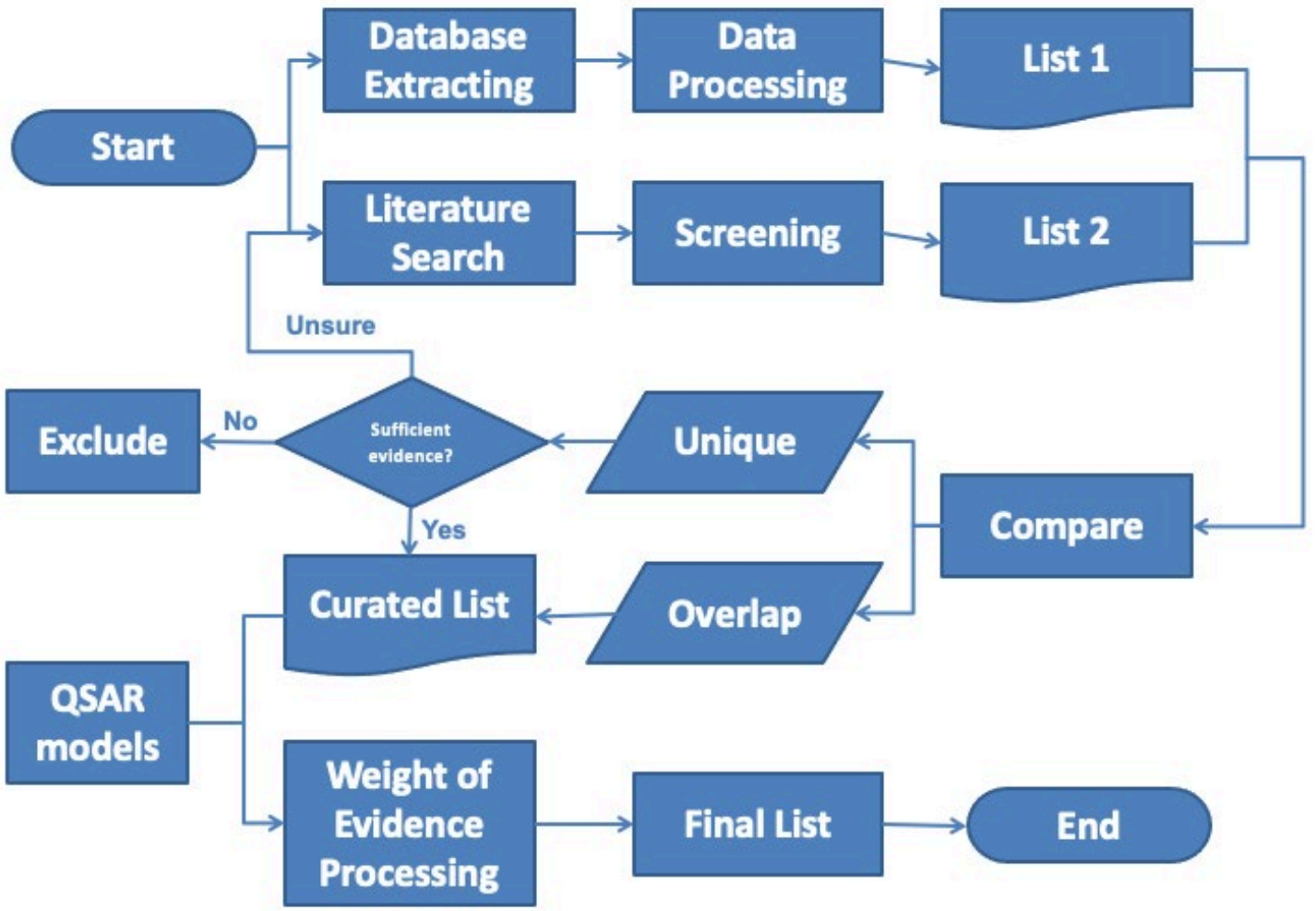
2024 Bi Biocompatibility Insights

Biocompatibility Insights 2024

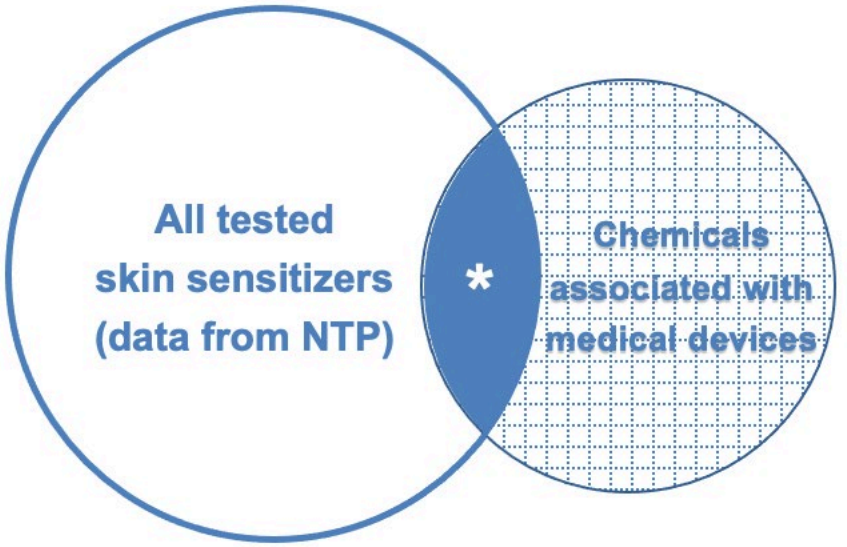
REGION SKÅNE

If contact allergy to defined substances are found associated with risk settings this gives support for possible primary and secondary prevention – but the information must reach the responsible for risk assessments.

Approach


Start
Database Extracting
Data Processing
List 1
Literature Search
Screening
List 2
Unsure
Exclude
No
Sufficient evidence?
Unique
Compare
Yes
Curated List
Overlap
QSAR models
Weight of Evidence Processing
Final List
End

Workflow 1



* Target: skin sensitizers released from medical devices

Compare a comprehensive list of compounds extracted from medical devices to a comprehensive list of known skin sensitizers.

Workflow 2

Systematic review of the available clinical, animal, and in vitro data to determine whether the compounds initially identified in the literature as skin sensitizers are accurately characterized.

	Count
Case Report	31
Epidemiological Study	58
Toxicological Study	18
Review	16

Categories of retrieved literature

Combined

The intersection of the two datasets:62 chemicals found in both List 1 and List 2, 82 chemicals were excluded from List 1 due to the lack of human data, the current curated list contains 196 chemicals.

Chemical Name	CAS Number	Suspected Case	Product type
2-octyl cyanoacrylate	133978-15-1	32	Adhesive
2-hydroxyethyl methacrylate	868-77-9	27	Adhesive
Isobornyl acrylate	5888-33-5	18	Rubber / Plastic
Abetic acid (Colophony)	514-10-3 (8050-09-7)	15	Adhesive / Cream

Table Most reported skin sensitizers released from medical devices and associated product types

WoE

Developing Weight of Evidence (WoE)

Clinical data:

- Quality of study

- sample size

In silico method analysis:

- PPV / NPV

- EC_3

categorization for each compound to indicate its skin sensitization potential and potency.

How will we use the results of the project?

Characterize the chemical space of skin sensitizers released from devices.

Evaluate the ability of QSAR models to predict skin sensitization potential of compounds within a context of use that is specific for medical devices.

Make the curated list available to dermatologists and patients to help them make more informed decisions about the use of medical devices containing specific skin sensitizing compounds.

Questions and discussion

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