REACH SVHC Database

Overview of upcoming ECHA REACH SVHC Database

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VP Consulting Services

Claigan

Overview - Agenda - REACH SVHC Database

- Introduction
- EU Recall 2019
- REACH Regulation Article 33
  - Definition of an Article
  - High risk materials
- Example REACH SVHC Declaration
- ECHA Database
  - Overview
  - Data summary
  - Data details
  - Example outputs
- Brief sojourn on how bad an idea full material declarations are
- Solutions
- Q&A

Webinar is 50 minutes with 10 minutes of Q&A (hopefully)

Claigan REACH SVHC Services

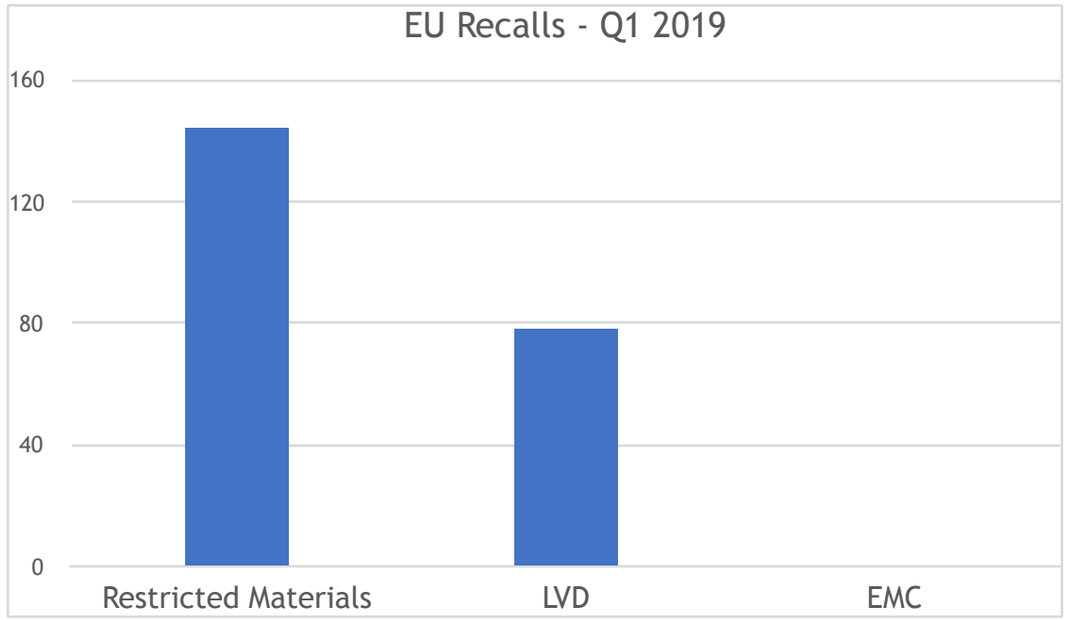
- Product testing
  - High volume lab for REACH SVHC testing
    - Plus RoHS (+phthalates), REACH SVHC, POP, Prop 65..

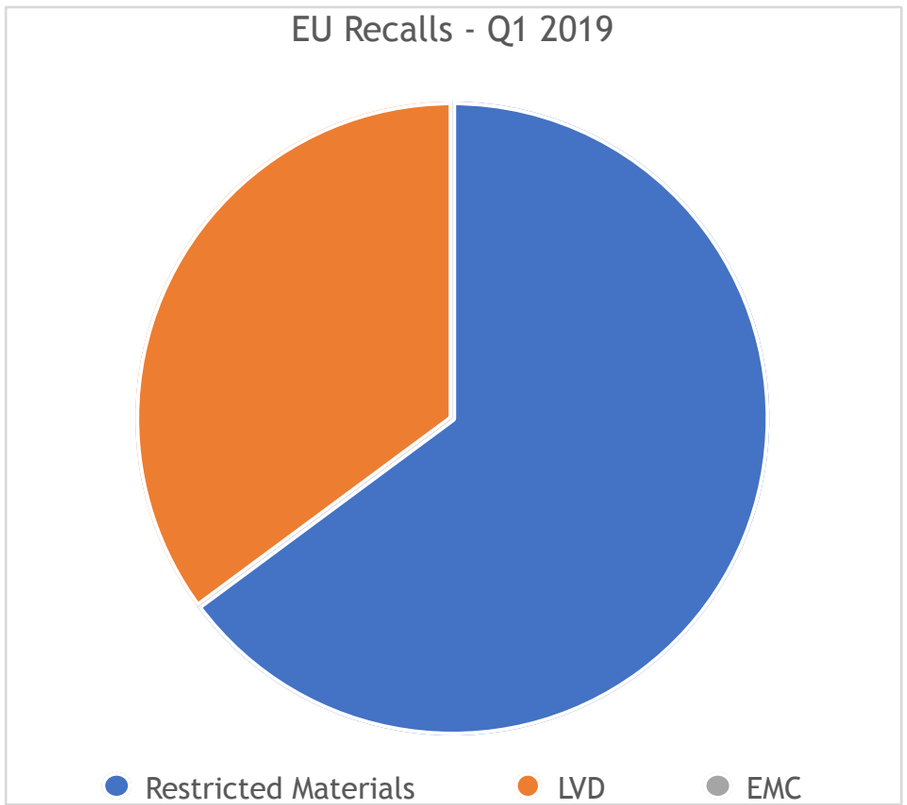
- Training and education (onsite)
  - 1/2 day education
  - 1/2 day product evaluation and REACH SVHC declaration writing

Q&A

EU Recalls - Q1 2019

Regulation	Recalls
Restricted Materials	144
LVD	78
EMC	0





2021
Substance of Concern Database - EU

- Database
  - Manufacturers to register products and their SVHCs in products in IUCLID by Jan 5 2021

- Update
  - Funding secured for full database development
  - More details on content expected this summer
  - Plans on track to have full system ready in 2020
  - Manufacturers to register products placed on the market after 5 January 2021
    - Barring any delays

ECHA
EUROPEAN CHEMICALS AGENCY

REACH SVHC Declaration

- Article 33 of REACH Regulation (1907/2006)
  - Suppliers of articles must communicate REACH Substances of Very High Concern (SVHC) > 0.1% w/w in an article they provide <u>to their customer</u>
  - Suppliers of consumer products to the end consumer only need to supply a declaration within 45 days of a consumer request
    - Sales to retailers do not benefit from the 45 days

- Based on the decision by the European Court of Justice (ECJ)
  - Component articles of complex articles are articles and require declaration

Summary - What is an Article?

- **Component requires an SDS**
  - Not an article
  - Examples
    - solder, glue, paint

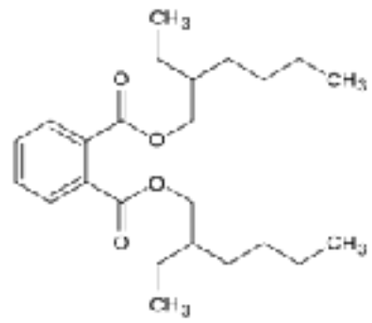

  - REACH SVHC communication requirements do not apply until added to an article

- **Component does not require an SDS**
  - Article
  - Examples
    - resistor, screw, wire


  - REACH SVHC communication requirements apply

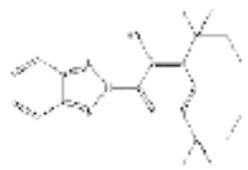
Commonly Declared SVHCs under Old Definition

- Phthalates (DEHP, BBP, DBP, DnHP, DHNUP)
  - Plasticizers
  - Common between 5% to 30% w/w in
    - PVC, buna-n, buna-s, vinyl, sealants, neoprene

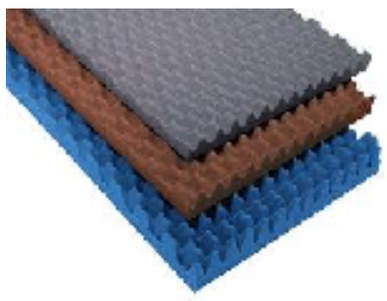


- 1, 2-dimethoxyethane (EGDME)
  - Common between 1% to 4% w/w in
    - Lithium manganese batteries

- UV stabilizers (UV-320, 327, 328, and 350)
  - in outdoor / UV rated plastics



- Flame retarded polyurethane
  - Tris(2-chloroethyl)phosphate (TCEP)



Some Specific Impacts

- Component types more likely to be declarable under the new definition
  - Internal PVC hook up wires (phthalates and SCCP)
  - Extruded PVC (BPA)
  - Buna-n or PVC gaskets (phthalates)
  - PVC labels (phthalates)
  - Electrical (vinyl) tape (phthalates and TXP)
  - Label adhesives (NPEO)
  - Fibre optics coating (NPEO)
  - Buzzers / transducers (PZT)
  - Kapton and Spandex (DMAC)
  - Closed cell foam (ADCA)
  - Brass, steel, aluminum (Pb metal)
  - Silicone rubber (D4/D5/D6)

Personal Care Products
Siloxanes and PFOA

Moisturizers and Conditioners → Silicone Gel (Dimethicone or Decamethylcyclopentasiloxane D5) → Bioaccumulants (REACH SVHC)

Traps moisture in

Makeup → PTFE or C9-15 Fluoroalcohol Phosphate (PFOA) → Bioaccumulant and Carcinogen (REACH SVHC Prop 65)

'Silky Texture'

REACH SVHC Declaration

- Compliance is a REACH SVHC Communication
- Example

Re: REACH Substances of Very High Concern (SVHC)

Jan 16 2019

Under Article 33 of EU REACH Regulation (1907/2006), ACME Co. has a duty to communicate to our customers the presence of SVHCs in excess of 0.1% by weight of articles (as defined by Court of Justice of the European Union Case C-106/14) contained in our products.

ACME Co. reviewed its products for the presence of the one hundred and ninety-seven (197) SVHC substances on the EU SVHC Candidate List as of 15 January 2019.

No SVHCs were found to be present in ACME Co. products in excess of 0.1% except as noted below. This determination is based on engineering evaluation, testing and supplier declarations and is correct to the best of ACME Co.'s knowledge.

Notes –

1. Internal, external cables and/or wires may contain Bis (2-ethylhexyl) phthalate (DEHP) (EC# 204-211-0) > 0.1% w/w.
2. Silicone components and materials may contain Dodecamethylcyclohexasiloxane (D6) (EC# 208-762-8) Decamethylcyclopentasiloxane (D5) (EC# 208-764-9) Octamethylcyclotetrasiloxane (D4) (EC# 209-136-7) >0.1%
3. Brass, aluminum, and steel components contain Lead >0.1% (EC# 231-100-4)
4. EVA foam may contain Diazene-1,2-dicarboxamide (C,C'-azodi(formamide) (EC#

Current REACH SVHC Declaration vs ECHA Database

- Database is
  - Centralized electronic version of what is already required
- Should be very little difference between the two except format
- The main difference is that the database ensures that companies actually meet their legal requirements under Article 33 of REACH Regulation
- And the data is better available to waste processors and to consumers

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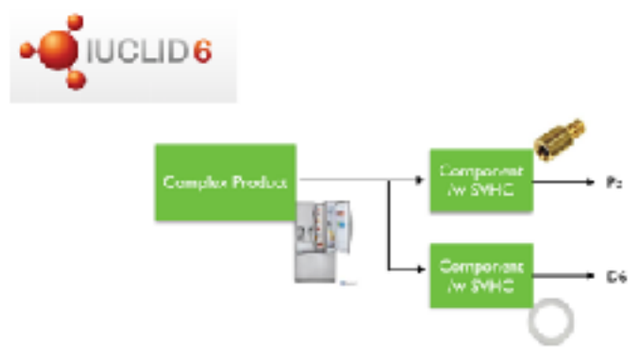
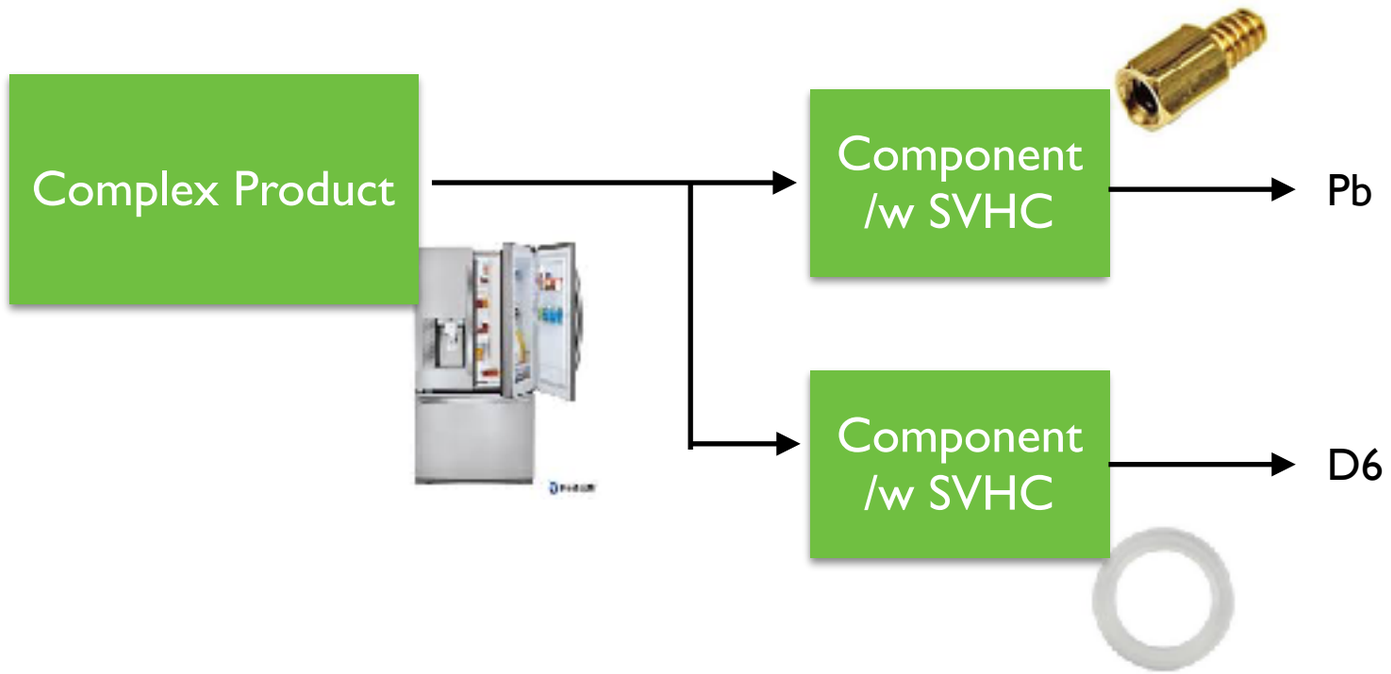


Substance of Concern Database - Example



2021
Substance of Concern Database - EU

- Declaration by
  - Complex product
    - with sub declaration for each article with a declarable REACH SVHC
    - in absence of the sub-component being declared by the original manufacturer, the importer of the complex product needs to create the declaration for
      - complex product, and
      - each component with a declarable REACH SVHC

Principal Data

- Main data
  - Administrative/legal entity data
  - Article/complex object data
  - Candidate List substance data (REACH SVHC)
  - Safe use information

Administrative / Legal Entity Data

- Administrative Details
  - Company name*
  - Company's contact details*
  - ECHA's company identifier (e.g. company UUID)#
  - Contact person (details)&

- * Mandatory
- # Mandatory but internal use only
- & Optional

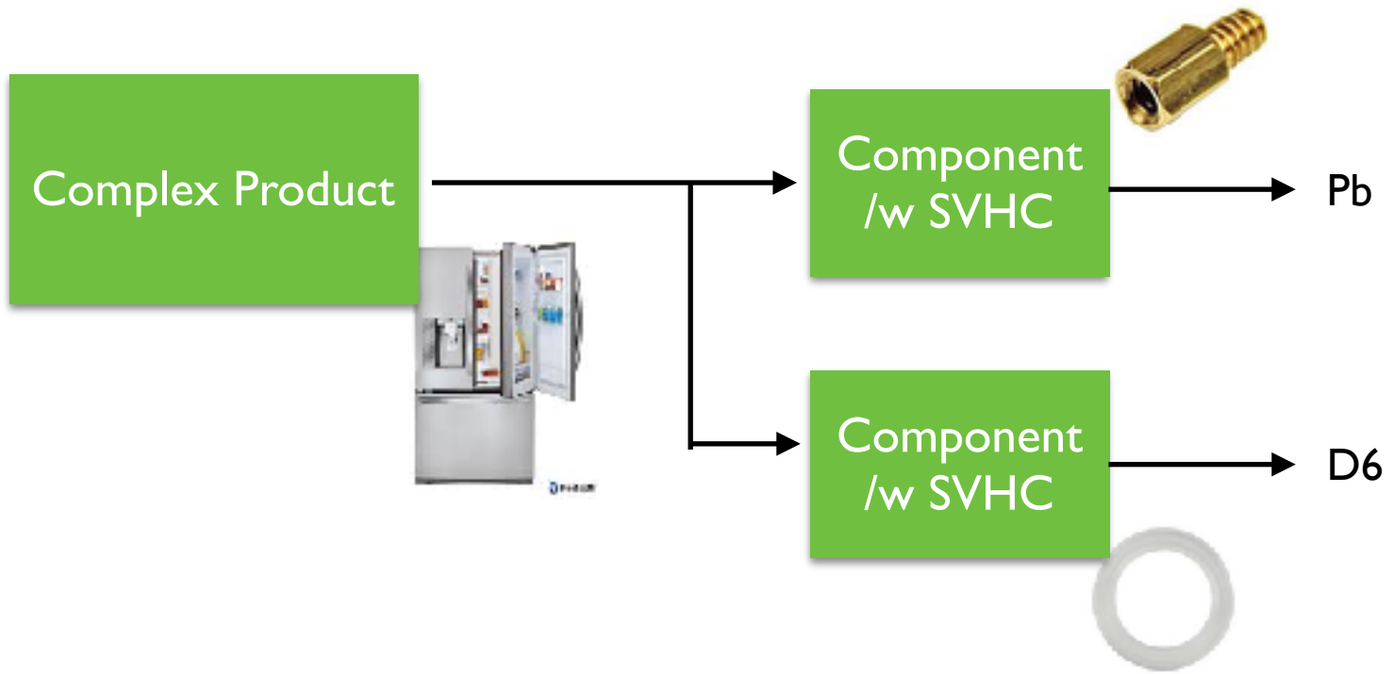
Substance of Concern Database - Product Identification

- Complete trade name
- Internationally recognised number/code
  - European International Article Number (EAN)/bar code,
  - Universal product code (UPC),
  - International standard book number (ISBN),
  - RFID, or
  - QR code
- Brand [N/A as an option]
- Model/type [N/A as an option]
- Other identifiers
  - picture, weight, dimensions, quantify, colour, etc..

Substance of Concern Database - Mandatory Info - Complex Article

- Complex article information
  - Categorisation of the complex object
    - Article/complex object-based category(ies) (CN customs code)
  - Complex object used by workers/consumers
  - Identification of the articles containing Candidate List substances in the complex object
    - and linking to sub component
    - does not require listing of subcomponents without SVHCs
- Safe Use Information

Substance of Concern Database - Example



Substance of Concern Database - Mandatory Info - Declarable Component

- Simple article (component) information
  - Categorisation of the article
    - Material-based category(ies) (material description)
      - ex. plastic - thermoplastic - PVC
    - Article/complex object-based category(ies) (CN Customs Code)
  - Article used by workers/consumers
  - Concentration of the substance in the article:
    - ≥ 0.1% w/w and < 0.3% w/w;
    - ≥ 0.3% w/w and < 1.0% w/w;
    - ≥ 1.0% w/w and < 5.0% w/w;
    - ≥ 5.0% w/w and < 10.0% w/w;
    - ≥ 10.0% w/w
  - Safe use information

Articles
Complex Object Codes

- Based on United Nations Standard Products and Services Code (UNSPSC) classification scheme
- ie. UNSPSC Commodity Code
- Example - pencil sharpener

UNSPSC Codes Commodity: 44121619

This is Commodity Code 44121619 in UNSPSC Codes, the Commodity Name is Manual pencil sharpener, more detail is as below.

Segment: 44000000
Segment name: Office Equipment and Accessories and Supplies
Family: 44120000
Family name: Office supplies
Class: 44121600
Class name: Desk supplies
Commodity: 44121619
Commodity name: Manual pencil sharpener

Articles
Material Categories

- Example materials categories
  - Based on ECHA's R12 Guidance on use description
    - Stone
    - Ceramic
    - Paper
    - Plaster
    - Fibre
    - Rubber
    - Cement
    - Leather
    - Wood
    - Glass
    - Metal
    - Plastic
    - Other

Articles
Material Categories

- With further subgroups

Group	Subgroup	Polymer	…
Plastics	Thermoplastics[4]	- polyethylene terephthalate - high density polyethylene - low-density polyethylene - polyvinyl chloride - polypropylene - polystyrene - etc.	…
	Thermosets[2]	- acrylic resins - polyesters - polyvinyl esters - etc.	…

Substance of Concern Database - Example - with more data

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IUCLID 6

Complex Product

Model XXXX
84182100

Component /w SVHC

Metal
Copper Metal Alloy

Pb

1 to 5%

Component /w SVHC

Plastic
Thermoset
Silicone

D6

0.1 to 0.2%

Substance of Concern Database - Safe Use Information

- Example safe use instructions
  - Advice to workers:
    - Wear respiratory protection in processing operations generating dust (e.g. grinding, drilling)
    - Avoid prolonged direct contact with skin during use
  - Advice to consumers:
    - Avoid prolonged direct contact with skin during use
    - Keep out of reach of children
    - Keep away from heat, hot surfaces, sparks, open flames
    - Do not mix with municipal waste
    - For outdoor use only
  - Advice to waste treatment operators:
    - Dispose of as hazardous waste
    - Waste incineration is recommended

Safe Use Information

- In practice
  - Safe use instructions will be dictated by
    - Classification
      - CMR, EDC, bioaccumulant, respiratory sensitizer, etc..
    - Exposure
      - Contact, inhalation, disposal
      - Use versus installation

- With similar warning for similar SVHCs in the same materials

Substance of Concern Database - Example - with safe use

Claigan

IUCLID 6

Complex Product

Model XXXX
84182100

Component /w SVHC

Metal
Copper Metal Alloy

Pb

1 to 5%

Avoid prolonged direct contact with skin during use
Wash hands after contact
Keep out of reach of children
Do not mix with municipal waste

Component /w SVHC

Plastic
Thermoset
Silicone

D6

0.1 to 0.2%

Do not mix with municipal waste
Do not flush or pour down drain

Worst Thing You Could Do - Full Material Declaration

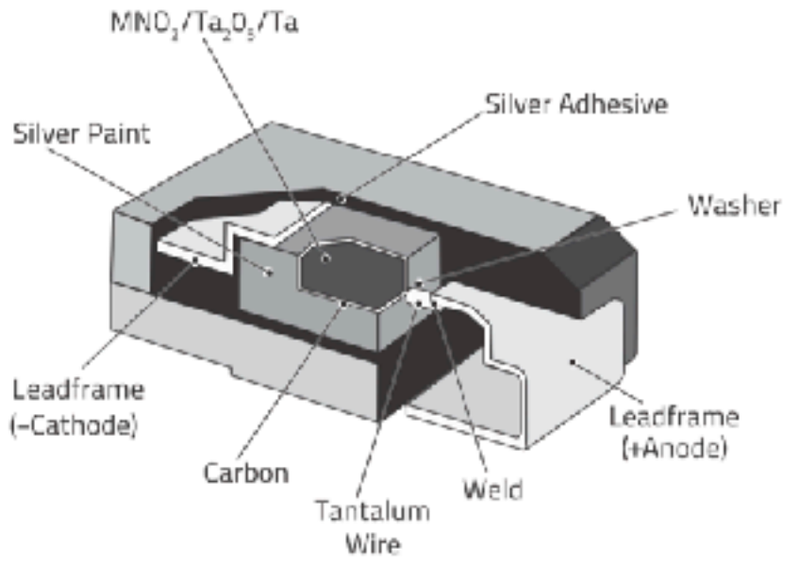
- Full material declaration is a horribly bad idea
  - Mostly fabricated ('made up') data
  - Additives in polymers are not declared
    - Flame retardants, plasticizers, monomers, antioxidants, impurities, and stabilizers
      - *examples - BPA, styrene, cyclosiloxanes, PFOA, SCCPs, and basically all new restricted substances*
  - Does not allow for alternative parts
  - Non-standardized data
  - Does not handle volatile materials

- Creating an accurate REACH SVHC declaration for your product by guesswork will generally be more effective than full material declaration

Side by side -
Same part. Two different manufacturers

Material declaration Data Sheet

Part Name	Material Name	Content (g)	Substance Name	Content (wt%, mg)	CAS NO
Element	Tantalum pellet	0.1300	Tantalum	41.490	7440-25-7
Element	Nitrate Solutin	0.0185	Manganese dioxide	5.904	1313-13-9
Element	Carbon paste	0.0036	Graphite	1.149	7782-42-5
		0.0008	Ammonium Hydoroxide	0.239	1336-21-6
Element	Silver paste	0.0068	Silver	2.170	7440-22-4
		0.0008	Acrylic resin	0.239	9011-14-7
Element	Conductive glue	0.0017	Silver	0.543	7440-22-4
		0.0003	Epoxy resin	0.093	25068-38-6
Terminal	Lead Frame	0.0220	42alloy	7.021	7439-89-6
		0.0008	Nickel	0.252	7440-02-0
		0.0007	Tin	0.207	7440-31-5
Exterior Mold	Mold resin	0.0920	Silica	29.362	60676-86-0
		0.0205	Epoxy resin	6.543	29690-82-2
		0.0150	Phenol resin	4.787	9003-35-4



Size	Part Name	Total Part Wt. (mg)	% Of Total Wt.	Substance Name	% Of Total Part Wt.	CAS No.	% Weight	Mass (mg)
'A' Case	Tantalum Anode	24.4772	41.77	Tantalum	36.63	7440-25-7	15.30	8.9658
				Manganese	20.06	7439-96-5	8.38	4.9107
				Silver	25.76	7440-22-4	10.75	6.2995
				Oxygen	11.83	7782-44-7	4.96	2.8948
				Carbon	5.29	7440-44-0	2.17	1.2716
				Flouring	0.43	7782-41-4	0.18	0.1055
				Misc.	0.12	proprietary	0.05	0.0293
	Leadframe	13.5011	23.21	Copper	57.73	7440-50-8	13.40	7.8524
				Nickel	17.15	7440-02-0	3.98	2.3323
				Zinc	15.36	7440-66-6	3.56	2.0862
				Tin	9.00	7440-31-5	2.09	1.2247
				Iron	0.22	7439-89-6	0.05	0.0293
				Misc.	0.55	proprietary	0.13	0.0762
	Molding case	20.5217	35.02	Oxygen	42.80	7782-44-7	14.99	8.7861
				Silicon	33.12	7440-21-3	11.60	6.7976
				Carbon	19.99	7440-44-0	7.00	4.1020
				Iron	0.77	7439-89-6	0.27	0.1582
				Misc.	3.31	proprietary	1.16	0.6798
	Totals	58.60	100.00				100.00	58.60

Full Material Declarations - Advantages

- Things that full material declarations are good for
  - Being the example in software demos
  - Selling software to equipment manufacturers
  - Causing product recalls

Claigan REACH SVHC Services

- Product testing
  - High volume lab for REACH SVHC testing
    - Plus RoHS (+phthalates), REACH SVHC, POP, Prop 65..
    - We have tested thousands of complex products for REACH SVHCs

- Quoting
  - We just need a picture, weblink, or description of the product

Claigan REACH SVHC Services

- ***Have a lot of products and do not even know where to start?***
- REACH SVHC Onsite
  - 1/2 day education
  - 1/2 day product evaluation and REACH SVHC declaration writing
- Advantages
  - Tangible
  - Handles a wider range of products
  - Provides a better knowledge foundation to leverage and maintain declarations across a wider product range

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Q&A