## REACH<sup>1</sup> ARTICLE 33 DECLARATION ON SUBSTANCES IN ARTICLES<sup>2</sup> - INCL. WFD/SCIP DATA

According to Article 33 ('Duty to communicate information on substances in articles') par. 1 of the EU REACH Regulation any supplier of an <u>article</u> containing a Substance of Very High Concern ("SVHC") identified in the latest European Chemicals Agency (ECHA) <u>Candidate List</u> (hereafter: **"CL SVHC"**) at the time of supply in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

In addition, according to Article 9(1)(i) of the revised Waste Framework Directive (WFD)<sup>3</sup> as transposed into national laws, the supplier shall also provide this information to ECHA as from 5 January 2021 for its Substances of Concern in Products (SCIP) Database (DB) established under WFD Article 9 par. 2 (SCIP notification); to this end ECHA has set out specific submission requirements.<sup>4</sup> The transmission of SCIP-related information (such as SCIP number and data) in the supply chain, e.g. as part of a REACH Article 33 declaration, is not mandated by law, but may be recommended and agreed in contracts.

IN ORDER FOR US TO COMPLY WITH REACH ARTICLE 33 PAR. 1 – AND AT THE SAME TIME SUPPORT YOUR COMPLIANCE WITH WFD/SCIP REQUIREMENTS (voluntary fields below in Italics) – WE HEREWITH DECLARE THE FOLLOWING:

## **A. SUPPLIER DETAILS**

Supplier name	
Supplier contact (name, phone, email, etc.)	
Supplier address and country	
(Other supplier identifiers)	

#### **B. PRODUCT DETAILS**

Product name	
SCIP number (if available)	
URL link to your Article Factsheet in the <u>SCIP DB</u>	
(SCIP) Primary Article Identifier (e.g. part number)	
(SCIP) Article category (based on CN/TARIC codes)	
(Other article identifiers)	

<sup>&</sup>lt;sup>1</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 20106 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

<sup>&</sup>lt;sup>2</sup> Declaration drawn up based on ECHA Guidance on requirements for substances in articles (Version 4.0 – June 2017).

<sup>&</sup>lt;sup>3</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as revised by Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018.

<sup>&</sup>lt;sup>4</sup> For further details see <a href="https://echa.europa.eu/scip">https://echa.europa.eu/scip</a>.

## C. INFORMATION ON CL SVHC(S) THAT IS (ARE) OR MAY BE PRESENT > 0.1% IN THE ARTICLE

Date of latest ECHA <u>Candidate List Package</u> used:						
CL SVHC(s) are or may be present > 0.1% w/w in			YES ☐ (fill in table below and other sections)			
the product/component article:			NO ☐ (go directly to E.)			
No.	CL SVHC name	CAS number (if available)	EC number (if available)	Component article / sub- assembly containing the CL SVHC (if available)	(SCIP) Material category*	(SCIP) Mixture category (EuPCS)*
1				,		
2						
	Please add more rows as needed for each CL SVHC				·	

# D. ADDITIONAL SAFE USE INFORMATION (SUI) GIVEN THE PRESENCE OF THE CL SVHC(S) LISTED ABOVE (C.)

If available and relevant to allow safe use of the article throughout the whole life cycle including service life, disassembly and waste/recycling stage (e.g. info on the more specific location of the CL SVHC or disassembling instructions. You may also refer to and attach applicable dedicated manuals or other use instructions.)

[Insert free text or URL link, if you have available and relevant SUI]	
[Insert free text of OKE link, if you have available and relevant 301]	

## **E. BEST KNOWLEDGE**

I declare, to my company best knowledge, that all the information provided in this declaration are complete and correct, and based on information on the ECHA website on the day of the declaration.

Declared by (name and title)	
Contact (email, phone)	
Date of declaration (DDMMYYYY)	
(Other)	

<sup>\*</sup>Only either the material category or the mixture category need to be provided, not both.

<sup>&</sup>lt;sup>5</sup> If the presence above 0.1% cannot be excluded based on the article supplier's reasoned judgment.

<sup>&</sup>lt;sup>6</sup> <u>Note</u>: For assemblies of articles the calculation of the 0.1% threshold has to be done in relation to each component article as such making up the assembly (Judgment of the Court of 10 September 2015 in Case C-106/14 – available <u>HERE</u>).

#### **EXPLANATORY ANNEXES TO THE DECLARATION TEMPLATE**

The present template is a revision of and replaces the previous document ref. MPTB-RL-TPL-0010, especially to take into account the introduction of WFD/SCIP reporting requirements to ECHA since 2018, and in order to provide a number of clarifications regarding its use in the following explanatory annexes:

- Annex 1 FILLING INSTRUCTIONS AND EXPLANATIONS FOR THE TEMPLATE
- Annex 2 KEY TERMS AND DEFINITIONS
- Annex 3 QUESTIONS & ANSWERS
- Annex 4 VERSION HISTORY

#### Disclaimer

The information in this document (document and annexes) reflects the opinion of members of the Materials and Process Technology Board (MPTB) from space industry, national space agencies, and ESA. It is not considered a requirement and any action to the described issue is subject to project or programme decision, nor a comprehensive treatment of the subject matter. The information is intended for guidance only and whilst it is provided in utmost good faith and has been based on the best information currently available and adequate technical standards, is to be relied upon at the user's own risk. No representations or warranties are made with regards to its completeness, or accuracy and no liability will be accepted by the MPTB nor any organisation participating in the MPTB for damages of any nature whatsoever resulting from the use of or reliance on the information.

BEFORE FINALISING A DECLARATION BASED ON THE ABOVE TEMPLATE, PLEASE MAKE SURE THAT YOU REMOVE THIS PAGE AND THE SUBSEQUENT EXPLANATORY ANNEXES AS WELL AS THE REFERENCE "MPTB-RL-TPL-0092, version 1.1 of 22.1.2024" IN THE FOOTER!

## ANNEX 1 – FILLING INSTRUCTIONS AND EXPLANATIONS FOR THE TEMPLATE

Section	Data field	Filling instruction / explanation
A. SUPPLIER DETAILS	(Other supplier	This is an optional field, to fill in depending on your
	identifiers)	organisation's internal procedures and/or recipient
	,	needs.
		If applicable: Provide further information on the issuing
		facility of the legal entity.
B. PRODUCT DETAILS	Data fields	Please note that the provision of these data in the supply
AND C. INFORMATION	exclusively related	chain / as part of REACH Article 33 declarations is <u>not</u>
ON CL SVHC(S) THAT	to SCIP submission	legally mandatory unless contractually agreed.
IS (ARE) OR MAY BE		Nevertheless, the provision of these data is important for
PRESENT > 0.1% IN		the customer to be able to comply with his own SCIP
THE ARTICLE		notification duties and/or also be able to verify the
		declaration contents in ECHA's SCIP Database published.
B. PRODUCT DETAILS	ECHA SCIP number	The SCIP number is an alphanumerical identifier assigned
	(if available)	by ECHA to the initial SCIP notification of an article in
	,	order to identify unambiguously unique SCIP
		notifications available in the SCIP Database (same Legal
		Entity, same Primary Article Identifier). The recipient of
		the article may use the SCIP number in order to verify
		the data related to it (such as the list of CL SVHCs) from
		the SCIP Database published at
		https://echa.europa.eu/scip-database and/or to submit
		his own SCIP notification based on ECHA's simplified
		notification options (see ECHA guide).
		Please note that non-EU/EEA suppliers of articles cannot
		obtain an ECHA SCIP number for their own legal entity.
		Therefore, they cannot fill in this field when providing a
		declaration for their product according to the template.
	Link to your Article	Please note that non-EU/EEA suppliers of articles do not
	Factsheet in the	have this option for their own legal entity, because they
	SCIP Database	cannot make SCIP notifications in their own name.
	Primary Article	A numerical or alphanumerical identifier, in the SCIP
	Identifier (e.g. part	Database context, assigned by the duty holder at his own
	number)	discretion to the article as such or to the complex object
		and the identification of its type.
	Article category	Classifies an article as such (with CL SVHCs) or a complex
	(based on CN/TARIC	object (incorporating several such articles) according to
	codes)	its function/use from a harmonised list of 10-digit
		CN/TARIC codes and descriptions, which is based on the
		TARIC list (see <u>Annex 2</u> ). Note that some EU TARIC codes
		are not valid for SCIP.
	(Other article	This is an optional field, to fill depending on your
	identifiers)	organisation's internal procedures and/or recipient
		needs
C. INFORMATION ON	Date of latest ECHA	Please refer to the date of the latest Candidate List
CL SVHC(S) THAT IS	Candidate List	reference substances package for SCIP notifications
(ARE) OR MAY BE	Package used:	available at <a href="https://echa.europa.eu/candidate-list-">https://echa.europa.eu/candidate-list-</a>
PRESENT > 0.1% IN		package, e.g. "June 2023 Candidate List Package"
THE ARTICLE		
	CL SVHC(s) are or	If you tick the "NO" box, please note that such
1	may be present >	"negative" declaration is voluntary from a REACH

0.1% w/w in the	Regulation point of view but may be required
product/component	contractually. It may also be beneficial e.g. to replace a
article as such:	previous "positive" declaration after chemical analysis.
CL SVHC name, CAS	Please refer to the <i>identifiers</i> of the latest Candidate List
number, EC number	reference substances package for SCIP notifications
	available at <a href="https://echa.europa.eu/candidate-list-">https://echa.europa.eu/candidate-list-</a>
	<u>package</u>
Material category	An ECHA SCIP data submission element, according to
	which the identification of the material the article
	(containing the CL SVHC) is made of, from a picklist
	provided by ECHA.
Mixture category	An ECHA SCIP data submission element based on the
(EuPCS)	European Product Categorisation System (EuPCS) to
	identify the mixture containing the CL SVHC(s)
	incorporated in a further processing step (e.g. coating) of
	an article or incorporated when joining or assembling
	two or more articles in a complex object (e.g. adhesive,
	solder), from a picklist provided by ECHA.
(Other)	This is an optional field. Examples for possible other
	signatory information:
	signature and stamp
	Contact details of REACH expert (in case clarification is
	needed)
1 (	product/component article as such: CL SVHC name, CAS number, EC number  Material category  Mixture category (EuPCS)

## **ANNEX 2 – KEY TERMS AND DEFINITIONS**

Term	Definition
Article (as such)	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. (REACH Article 3(3)).
	<ul> <li>Pursuant to the "once an article, always an article" principle confirmed by the Court of Justice of the European Union (CJEU), such an 'article' remains an 'article' also if assembled or joined with other articles (forming 'complex objects') until it becomes 'waste' as defined in the Waste Framework Directive (judgment of the CJEU of 10 September 2015 in case C-106/14).</li> </ul>
	<ul> <li>'Substances' and 'mixtures' are not articles and are subject to Safety Data Sheet requirements under REACH (if classified as hazardous).</li> </ul>
Candidate List (CL)	The Candidate List refers to the list of substances of very high concern (SVHCs) from which the substances to be included in Annex XIV (list of substances subject to authorisation) are selected. It is the reference list for REACH Article 33 reporting and WFD/SCIP notifications.
Complex Object	The term is not defined in the REACH Regulation nor the WFD. According to ECHA (implementing the judgment of the CJEU of 10 September 2015 in case C-016/14) it refers to any object made up of two or more articles 'as such' (as defined in REACH Article 3(3)) which are assembled or joined together. The more articles such an object is made of, the more complex is the object.
European Economic Area (EEA)	All Member States of the European Union (EU) incl. French Guiana, as well as the non-EU EEA countries (e.g. Norway) applying EU REACH (incl. Article 33) and WFD/SCIP. This excludes third countries such as Russia, Turkey, the US, as well as Switzerland and the UK (after Brexit). However, for corresponding reporting obligations on SVHCs in articles in Switzerland and the UK, please see this document in ANNEX 3 – QUESTIONS AND ANSWERS (point 3. for UK and point 4. for Switzerland).
Supplier of an article	Any EU/EEA producer or importer of an article, distributor or other actor in the supply chain placing an article on the market' (REACH Art. 3(33)).
	<ul> <li>'Placing on the market' means Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (REACH Article 3(12)).</li> </ul>
	<ul> <li>'Importer' means a legal entity established within the EU/EEA who is responsible for import; import means the physical introduction into the customs territory of the EU/EEA (REACH Article 3(11)/(10)).</li> </ul>
TARIC	TARIC is the integrated Tariff of the European Union – TARIC – list, based on the Combined Nomenclature (CN) description and code [Annex I to Council Regulation (EEC) No 2658/87] (the relevant descriptions and codes must be selected). The TARIC list is also known as the EU product classification system. Both TARIC and the Combined Nomenclature are managed by the European Commission.

#### **ANNEX 3 – QUESTIONS AND ANSWERS**

#### 1. Who needs to comply with REACH Article 33 and WFD/SCIP?

With view to REACH Article 3(33) any of the following suppliers of articles containing a CL SVHC above 0.1% w/w need to comply with REACH Article 33 and WFD/SCIP:

- EU producers and assemblers,
- EU importers,
- EU distributors of articles and
- Any other actors who place articles on the market.

Sometimes the fulfilment of these roles can be unclear, and further analysis of the legal text, contracts in place and other circumstances of the case is required to determine e.g. who is the 'importer' or whether the product is 'placed on the market'. In such cases you are advised to seek qualified legal advice.

Please note that the non-EU EEA countries Norway, Iceland and Liechtenstein are also applying EU REACH (incl. Article 33) and WFD/SCIP (following incorporation into the EEA Agreement, see ECHA Q&A ID 1661).

## 2. My supplier is located outside EU/EEA (e.g. Switzerland, UK, US) – How do I get the required information for my REACH Article 33 and WFD/SCIP compliance?

You are strongly advised that your corporate compliance strategy contains a dedicated approach to handle such cases to meet your *duty of care*, as non-EU/EEA article suppliers are not legally required to report according to EU REACH Article 33 and are not eligible to submit SCIP notifications to ECHA in their own name. Therefore, non-EU/EEA companies cannot obtain an ECHA SCIP number for their own legal entity.

Key recommended elements of such pro-active compliance strategy include, but are not limited to:

- Contractual provisions to obtain the necessary compliance data from your non-EU/EEA supplier;
- Supplier inquiries (e.g. request them to fill in a declaration as per the above template, except for the ECHA SCIP number);
- Your expert judgment with regard to the presence of CL SVHCs in imported materials.

#### 3. What if my supplier is UK-based?

In principle after Brexit, UK-based suppliers of articles to the EU/EEA are now third country suppliers. As such they are not subject to EU WFD/SCIP Database nor EU REACH Article 33 reporting. For their own compliance purposes, EU/EEA importers of articles from UK-based suppliers are advised to proceed as with any other non-EU/EEA supplier (see above 2.). However, the following specific points should be noted:

- Suppliers based in Great Britain (England, Scotland and Wales) are subject to an identical provision for supply chain reporting in UK REACH Article 33, which applies in a Great Britain-only context. Please note that the corresponding SVHC Candidate List under UK REACH (available on the <a href="HSE website">HSE website</a> at <a href="https://www.hse.gov.uk/reach/candidate-list.xlsx">https://www.hse.gov.uk/reach/candidate-list.xlsx</a>) may differ from the EU REACH Candidate List.
- Suppliers based in Northern Ireland still continue to be subject to EU REACH, incl. EU REACH Article 33 and the EU REACH Candidate List for the duration of the Northern Ireland Protocol. However, WFD/SCIP does not apply in Northern Ireland either.

### 4. What if my supplier is based in Switzerland?

EU REACH and WFD/SCIP Database do not apply in Switzerland. For their own compliance purposes, EU/EEA importers of articles from Swiss-based suppliers are advised to proceed as with any other non-EU/EEA supplier (see above 2.).

It should be noted that Switzerland has enacted a similar provision to EU REACH Article 33. It can be found in Article 71 of the Chemicals Ordinance (ChemO) and applies in a Switzerland-only context. The corresponding Swiss SVHC "Candidate List" can be found in Annex 3 of the ChemO. Both ChemO and the latest version of Annex 3 are available on the website of the common notification authority for chemicals.

<u>Note</u>: The ChemO is largely harmonised with the European REACH and CLP Regulations. Nevertheless, there may be differences between the EU REACH Candidate List and Annex 3 of the ChemO (especially due to delayed updates of Annex 3 following EU Candidate List updates).

#### 5. What to do in case of outdated Article 33 declarations?

A common challenge for downstream article suppliers is the "outdating" of Article 33 declarations for components provided by the upstream supplier due to the bi-annual update of the EU REACH Candidate List; the reporting for the onward supply of the component/higher level assembly that incorporates it has to take into account the latest update of the EU REACH Candidate List at the time of onward supply. The upstream supplier is not legally obliged under EU REACH Article 33 to provide an updated declaration for a component supplied previously. Therefore, downstream article suppliers are advised to proceed as in other cases where the upstream supplier is not subject to the legal obligation (see above 2.).

## 6. How should I calculate whether a CL SVHC in my product exceeds the 0.1% w/w threshold?

Importantly – following the "once an article, always an article" principle confirmed by the CJEU with judgment of the CJEU of 10 September 2015 in case C-106/14 – the calculation of the w/w concentration of a CL SVHC must be based on the **smallest demountable article** containing that substance, and **not** on the **complex object/assembly as a whole**.

Exceptionally however, the calculation of the 0.1% w/w threshold of the CL SVHC will in some cases be with reference to the complex object or sub-component/assembly. This applies for example in case of coatings of complex objects, solders and adhesives to join articles as such or sub-components being complex objects. In such cases the Candidate List substance cannot be assigned to an article as such.

#### 7. Can I just forward an Article 33 declaration received from my supplier?

This is not advised, because it is you as the (downstream) article supplier who is legally responsible for the content of the Article 33 declaration for your entire product as you supply it. When preparing your own declaration, you will of course take into account Article 33 declarations received from your suppliers as an internal source of information.

#### 8. May I need to comply with other EU health and safety requirements concerning my product?

Yes of course. By providing a REACH Article 33 declaration suppliers of articles only report on CL SVHC(s) in their products and provide available and relevant additional safe use information in cases where the placing on the market is not restricted. Such restrictions (as well as applicable derogations, exemptions or other limitations of their scope) may be based e.g. on Annex XVII of the REACH Regulation (see e.g. entry 23 for cadmium) or Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances (RoHS) such lead in electrical and electronic equipment. Also WFD/SCIP requirements are to be complied with in addition to Article 33 reporting (therefore the transmission of minimum SCIP data is recommended in the Article 33 declaration template). Hence, both the supplier of the article and the customer (for its use) have to ensure for their activities and be able to prove in case of authority inspections that other applicable requirements are followed.

#### 9. Where can I get further information on REACH Article 33 and WFD/SCIP compliance requirements?

Here is a non-exhaustive list of important sources (as of 22.1.2024):

#### • ECHA website

- o ECHA Guidance on requirements for substances in articles, June 2017, Version 4.0
- <u>ECHA Requirements for SCIP notifications, October 2020</u> further language versions are available at https://echa.europa.eu/scip-support
- o ECHA SCIP webpages, including SCIP database
- o ECHA Questions and Answers

## National helpdesks and guidelines

E.g. in Germany: <u>BAUA REACH: Info "Articles – Requirements for Producers, Importers and Distributors, 4th, revised and expanded edition, September 2020; FAQ SCIP by Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit, 22 September 2022</u>

#### Industry sector guidelines:

- <u>Eurospace, Best-Practice Guidance for the European Space Sector to comply with SCIP notification, version 1.2, 19 September 2022</u>
- ASD Sectorial Guidance for WFD/SCIP implementation, Version 1.1 April 2022 incl. a detailed Q&A Section in Chapter 10
- o ASD Sectoral Guidance for Substances in Articles under REACH, Version 1 November 2017

10. Contact for further information: Reach.officer@esa.int

## **ANNEX 4 – VERSION HISTORY**

Version	Changes made
Initial version of 10.2.2022	
Updated version 1.1 of 22.1.2024	<ul> <li>Updated reference links in ANNEX 1 and ANNEX 3 (question 9.) prior to publication on ESCIES</li> <li>Added ANNEX 4 – Version history</li> </ul>