Dok.Nr. 0768

ungelenkte Kopie

ZIMMER

Statement on the REACH Regulation in accordance with Article 33 and SVHC in accordance with REACH Regulation Article 59

Dear customers and partners,

Thank you very much for your enquiry. We herewith would like to inform you on our obligations according to Article 33 of the REACH Regulation. On 1 June 2007, REACH, the new uniform European chemicals legislation, entered into force.

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.

REACH (Regulation (EC) No. 1907/2006) applies to both manufacturers and importers of chemicals and mixtures of chemicals who either manufacture chemical substances in quantities of 1 tonne or more or import them from non-EU countries. Registering these substances at the European Chemicals Agency (ECHA) head-quarters in Helsinki and submitting Chemical Safety Reports on the respective substances is mandatory.

Having checked and analysed the substances we use, we guarantee that the European Union REACH Regulation for Chemicals does not affect our mutual business relationship. We do not manufacture substances that are affected by REACH. The chemical substances that are contained in our products and that are potentially subject to registration are, in any case, registered by our upstream suppliers.

We comply with the "Duty to communicate information on substances in articles" in accordance with the statutory regulations in Article 33 and 59 of the REACH regulation:

 We are in constant contact with our raw material suppliers, making sure that they notify us if substances of very high concern (SVHC) from the candidate SVHC list are contained in our products in a concentration above 0.1 per cent by weight.

The supplier undertakes to provide a product ingredient declaration in accordance with the currently valid candidate list (SVHC - Candidate List of **S**ubstances of **V**ery **H**igh **C**oncern) immediately and unsolicited upon becoming aware of a border crossing or a change in the legal basis.

Dok.Nr. 0768

ZIMMER

Our European suppliers providing us with substances that are largely contained in our products are
also bound to notify us without being asked and without delay in case one of their delivered products contains SVHC of more than 0.1 per cent by weight.

We will inform you immediately in the event we receive such information from our suppliers and determine that also one of our products exceds the 0.1 per cent by weight threshold for a SVHC substance.

Since the validity of the REACH Regulation only covers the European Union, we conclude special
agreements with all our Non-EU suppliers who provide us with articles that are largely used to manufacture our products. Therefore, we make sure that our Non-EU suppliers notify us immediately in
writing in case one of their delivered articles contains more than 0.1 per cent by weight of a SVHC
substance.

For quite some time now, we have been maintaining a hazardous substances register in which we document substances used by us in order to ensure compliance with the REACH regulations. Thus, we make sure that we will be able to react adequately, should the given circumstances concerning chemical substances change significantly.

We also confirm that the delivered products are in compliance with the REACH Regulation Annex XVII, the GHS regulation and §3 ff. Ordinance on Hazardous Substances (GefStoffV) do not contain any prohibited or avoidable substances with the following hazard classes or hazard characteristics:

- Radioactive substances
- Explosive substances/mixtures and articles containing explosives,
   categories 1.1, 1.2, 1.3, 1.5 (H200, H201, H202, H203, H205)
- Self-reactive substances and mixtures of categories A, B (H240, H241)
- Organic peroxides of categories A, B (H240, H241)
- Acute toxicity category 1, 2 (H300, H310, H330)
- Category 1A, 1B (H350) carcinogenicity
- Germ cell mutagenicity of category 1A, 1B (H340)
- Reproductive toxicity category 1A, 1B (H360)
- Environmentally hazardous substances with water hazard class 3 (highly hazardous to water)

Dok.Nr. 0768



In compliance with the REACH Regulation Annex XVII, Entry 68, and the EU Regulation 2019/1021 (POP) Annex I, Part A, this also applies to perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds.

If you have any questions relating to the REACH Regulation, please do not hesitate to contact us.

Rheinau, 12.03.2024.

Best Regards,

Patrick Roth

B. Eng. |Specialist for occupational safety and hazardous substances officer

Phone: +49 7844 9138-5517 Mobil: +49 160 4189752

E-Mail: <a href="mailto:patrick.roth@zimmer-group.com">patrick.roth@zimmer-group.com</a>