baua: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

HAZARD ASSESSMENT

OUTCOME DOCUMENT

for

Undecafluorohexanoic acid (PFHxA)

EC No 206-196-6

CAS No 307-24-4

Member State: Germany

Dated: October 2017

Version 1.3

1. HAZARD SUBJECT TO ASSESSMENT

Undecafluorohexanoic acid, commonly identified by the abbreviation PFHxA, was selected for hazard assessment in order to clarify suspected hazard properties: PBT/vPvB or equivalent level of concern. Exempted from the evaluation are health effects for the human population and environmental endocrine disrupting properties.

2. OUTCOME OF HAZARD ASSESSMENT

The available information on the substance and the hazard assessment conducted have led the assessing Authority to the following considerations, as summarised in the table below.

Hazard Assessment Outcome	**Tick box**
According to the authority's assessment the substance does not have PBT/vPvB properties or properties of equivalent level of concern based on the currently available information.	
According to the authority's assessment the substance has PBT/vPvB properties or properties of equivalent level of concern.	x
According to the authority's assessment further information would be needed to confirm the PBT/vPvB properties but follow-up work is not relevant or carried out at present.	

This outcome is based on the REACH and CLP data as well as other available relevant information.

3. BASIS FOR REASONING

Because of the high energy of the carbon-fluorine bond it can be assumed that the short-chain perfluoroalkyl substance (PFAS)[1] PFHxA is as persistent as long-chain PFASs and does not undergo abiotic or biotic degradation at all under environmental conditions. PFHxA is regarded as a highly stable transformation product in which several precursors ultimately degrade. This extreme persistence is regarded as an incalculable hazard itself, as PFHxA will stay in the environment for decades to centuries.

The physicochemical properties of PFHxA show that it is a very mobile substance preferentially distributed in aquatic systems. Thus, once emitted to soil, PFHxA reaches underlying water bodies easily. Because of the low adsorption potential, PFHxA can only hardly, if at all, be removed from the environment. Where long-chain PFASs can be removed with activated carbon filters, this is not effective for short-chain PFASs. Thus, in case PFHxA reaches drinking water reservoirs, to date no effective measures exist to remove the substance from the water.

Due to persistency and mobility, PFHxA has the potential for long-range transport and is already detected in remote areas as for example in arctic biota or the European Alps.

Manufacturing and use of PFHxA precursors will increase, since these substances are used as alternatives for the long-chain PFASs. Thus emissions of PFHxA, the end-stage degradation product, will increase as well. Along with the expected increasing emissions of PFHxA, it will enrich in the environment leading to increased background concentration levels, especially in the aquatic systems. Hence, in the long-term, organisms may be permanently exposed to PFHxA, resulting in continuous internal concentrations in organisms.

[1] PFASs are divided into long- and short-chain representatives, depending on the length of the perfluorinated carbon chain. Long-chain perfluoroalkyl acids include perfluoroalkyl carboxylic acids with ≥ 7 perfluorinated carbons and perfluoroalkane sulfonic acids with ≥ 6 perfluorinated carbons.

Elimination half-lives of PFHxA are non-negligible: depending on the species, they range from a couple of hours to several days in some mammals including humans. These elimination half-lives are low in comparison with some long-chain PFASs, but still of concern, as PFHxA will remain for some time in the organisms. PFHxA has a considerable protein binding potential. However, it is to be investigated how toxicokinetical characteristics of PFHxA are influenced by its protein binding potential and as a consequence how concentrations in different tissues and organs are affected by this. In general, there is a high level of uncertainty, whether the permanent exposure with low concentrations of PFHxA may cause adverse effects in organisms. Even though the ecotoxicological data show that PFHxA is not highly toxic, sub-lethal long-term effects cannot be excluded.

PFHxA is known to enrich in plants and due to its water solubility especially in leaves and fruits. This enrichment in the edible parts of plants might pose a risk regarding distribution along the food chain, which has not yet been investigated. Field studies do not allow drawing a conclusion on a possible accumulation of PFHxA in organisms along the food chain.

In summary, PFHxA is not considered to be a PBT or vPvB substance as the substance does not meet the B- and T-criterion according to Annex XIII of the REACH regulation. However, the concerns attributed to PFHxA, are of equivalent level of concern to a PBT of vPvB substance according to Article 57(f) of the REACH regulation.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority.

Follow-up action	**Date for intention**	**Actor**
Annex XV dossier for SVHC identification	02 / 2018	DE
Annex XV dossier for Restriction	Following SVHC identification	DE