Message

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**Sent**: 11/28/2018 3:24:48 PM
**To**: Anderson, Steve [Anderson.Steve@epa.gov]; Askinazi, Valerie [Askinazi.Valerie@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Barkas, Jessica [barkas.jessica@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Blair, Susanna [Blair.Susanna@epa.gov]; Blunck, Christopher [Blunck.Chris@epa.gov]; Buster, Pamela [Buster.Pamela@epa.gov]; Canavan, Sheila [Canavan.Sheila@epa.gov]; Caraballo, Mario [Caraballo.Mario@epa.gov]; Carroll, Megan [Carroll.Megan@epa.gov]; Cherepy, Andrea [Cherepy.Andrea@epa.gov]; Christian, Myrta [Christian.Myrta@epa.gov]; Corado, Ana [Corado.Ana@epa.gov]; Davies, Clive [Davies.Clive@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Devito, Steve [Devito.Steve@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Drewes, Scott [Drewes.Scott@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Edmonds, Marc [Edmonds.Marc@epa.gov]; Elwood, Holly [Elwood.Holly@epa.gov]; Faeth, Lisa [Faeth.Lisa@epa.gov]; Farquharson, Chenise [Farquharson.Chenise@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Feustel, Ingrid [feustel.ingrid@epa.gov]; Frank, Donald [Frank.Donald@epa.gov]; Gibson, Hugh [Gibson.Hugh@epa.gov]; Gimlin, Peter [Gimlin.Peter@epa.gov]; Gorder, Chris [Gorder.Chris@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Grant, Brian [Grant.Brian@epa.gov]; Gray, Shawna [Gray.Shawna@epa.gov]; Groeneveld, Thomas [Groeneveld.Thomas@epa.gov]; Guthrie, Christina [Guthrie.Christina@epa.gov]; Helfgott, Daniel [Helfgott.Daniel@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kapust, Edna [Kapust.Edna@epa.gov]; Kemme, Sara [kemme.sara@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]; Krasnic, Toni [krasnic.toni@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Lee, Mari [Lee.Mari@epa.gov]; Lee, Virginia [Lee.Virginia@epa.gov]; Leopard, Matthew (OEI) [Leopard.Matthew@epa.gov]; Liva, Aakruti [Liva.Aakruti@epa.gov]; Lobar, Bryan [Lobar.Bryan@epa.gov]; Mclean, Kevin [Mclean.Kevin@epa.gov]; Menasche, Claudia [Menasche.Claudia@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Myers, Irina [Myers.Irina@epa.gov]; Myrick, Pamela [Myrick.Pamela@epa.gov]; Nazef, Laura [Nazef.Laura@epa.gov]; Ortiz, Julia [Ortiz.Julia@epa.gov]; Owen, Elise [Owen.Elise@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Passe, Loraine [Passe.Loraine@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Pratt, Johnk [Pratt.Johnk@epa.gov]; Price, Michelle [Price.Michelle@epa.gov]; Reese, Recie [Reese.Recie@epa.gov]; Reisman, Larry [Reisman.Larry@epa.gov]; Rice, Cody [Rice.Cody@epa.gov]; Richardson, Vickie [Richardson.Vickie@epa.gov]; Ross, Philip [Ross.Philip@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Santacroce, Jeffrey [Santacroce.Jeffrey@epa.gov]; Saxton, Dion [Saxton.Dion@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Selby-Mohamadu, Yvette [Selby-Mohamadu.Yvette@epa.gov]; Seltzer, Mark [Seltzer.Mark@epa.gov]; Sheehan, Eileen [Sheehan.Eileen@epa.gov]; Sherlock, Scott [Sherlock.Scott@epa.gov]; Simons, Andrew [Simons.Andrew@epa.gov]; Sirmons, Chandler [Sirmons.Chandler@epa.gov]; Slotnick, Sue [Slotnick.Sue@epa.gov]; Smith, David G. [Smith.DavidG@epa.gov]; Smith-Seam, Rhoda [smith-seam.rhoda@epa.gov]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]; Symmes, Brian [Symmes.Brian@epa.gov]; Tanner, Barbara [Tanner.Barbara@epa.gov]; Thompson, Tony [Thompson.Tony@epa.gov]; Tierney, Meghan [Tierney.Meghan@epa.gov]; Tillman, Thomas [Tillman.Thomas@epa.gov]; Tomassoni, Guy [Tomassoni.Guy@epa.gov]; Tran, Chi [Tran.Chi@epa.gov]; Turk, David [Turk.David@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Wallace, Ryan [Wallace.Ryan@epa.gov]; Wheeler, Cindy [Wheeler.Cindy@epa.gov]; Widawsky, David [Widawsky.David@epa.gov]; Williams, Aresia [Williams.Aresia@epa.gov]; Williams, Bridget [Williams.Bridget@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Wills, Jennifer [Wills.Jennifer@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]; Wright, Tracy [Wright.Tracy@epa.gov]; Yowell, John [yowell.john@epa.gov]
**Subject**: News Articles (For EPA Distribution Only)

**INSIDEEPA.COM ARTICLES**

Facing Subpoena Threat, Suit, EPA Limits Political Officials' FOIA Reviews

EPA has quietly issued a new policy that sets a schedule for political officials to review Freedom of Information Act (FOIA) releases and also requires prompt disclosures of the review, a policy that the agency is citing to head off a pending lawsuit challenging the practice as well as a possible subpoena from House Democrats in the next Congress.

## CHEMICAL WATCH ARTICLES

### Sweden sets new exemption fee for chemicals controls

27 November 2018 / Alternatives assessment & substitution, Cleaning products, Substances of concern, Sweden

The Swedish chemicals agency (Kemi) has said it will impose a new fee on all applications for exemptions from restrictions concerning industrial chemicals from 1 January.

A charge of SEK15,000 (€1,455) will be applied to such requests filed under a national chemicals legislation that bans the handling, import and export of certain substances, Kemi said.

Under this, it is possible to obtain an exemption – for example for methylene chloride and certain uses of mercury not covered by EU rules.

The new fee will now also apply to requests for derogations under the EU detergents Regulation, Kemi said.

Sweden currently has a SEK2,500 fee only on exemption applications for methylene chloride, one of the chlorinated solvents that has historically accounted for a vast majority of applications in the country. Trichloroethylene, another industrial solvent, came under the EU REACH umbrella in 2016, bringing the Swedish applications to an end.

The existing fee on methylene chloride has been the same for the past 20 years, Kemi said, and with all other exemption requests handled free of charge, the inspectorate has been left "underfunded".

The current fee structure is also not congruent with the principle of 'polluter pays' in environmental legislation, it added.

The agency has provisions to charge for a number of exemption cases from authorisations, but it "has chosen not to do this", Christophe Kellner from Kemi's chemicals inspectorate said.

Earlier this year, the European Commission revised the fees for REACH authorisation applications to encourage companies to apply together.

**Related Articles**

- Echa round-up

**Further Information:**

- Press release (in Swedish)

### Danish study finds high levels of PFASs in cosmetics

Some concentrations 'exceed' forthcoming REACH restriction limit

27 November 2018 / Alternatives assessment & substitution, Denmark, Personal care, PFCs, REACH

The Danish EPA has found high levels of perfluoroalkyl and polyfluoroalkyl substances (PFASs) in almost one third of 17 analysed cosmetics products.

PFASs are used in foundations, moisturisers, eye shadows, and shaving creams for their surfactant properties, which help creams to better penetrate the skin.

The EPA recently tested the products and said that, while one or more PFASs were identified in all the analysed products, the levels in six exceed those in forthcoming REACH restrictions.

For two products (both foundations) perfluorooctanoic acid (PFOA) was found in concentrations above the REACH restriction limit of 25 parts per billion (ppb) – or 25 nanograms per gram (ng/g) – which will enter into force on 4 July 2020.

Meanwhile, in six products concentration limits exceeded that of a proposed REACH restriction for C9-C14 perfluoroalkyl acids or perfluorocarboxylic acids (PFCAs).

Echa's Risk Assessment (Rac) and Socio-economic Analysis (Seac) Committees agreed to a restriction proposal for PFCAs last September.

Germany and Sweden submitted the proposal in a bid to prevent industry from switching from using PFOA-based substances to longer-chain PFCAs.

**Study findings**

The highest concentration of a single substance detected in the study was in a foundation at 3,340 ng/g perfluorohexanoic acid (PFHxA), while the highest concentration of total PFASs was in a concealer (10,700 ng/g).

The EPA's research was developed in three stages: a survey of PFASs in cosmetic products, a chemical analysis of these and analysis of total organic fluorine content in selected of the products.

It focused on the substances:

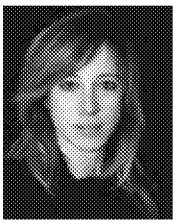
- perfluorooctanoic acid (PFOA);
- perfluorobutanoic acid (PFBA);
- perfluoropentanoic acid (PFPeA);
- perfluorohexanoic acid (PFHxA); and
- perfluoroheptanoic acid (PFHpA).

Agency head Magnus Løfstedt said the risk for consumers is not posed by "one of the measured concentrations in the products", but rather "if several cosmetics containing PFAS are used at the same time".

He recommended consumers use eco-labelled products.

Besides targeting cosmetics, over the last year Denmark has been raising awareness of the risks related to fluorinated substances in outdoor wear and cake packaging.

In related news, the Norwegian EPA has encouraged industry to prepare to use alternatives, when a restriction on the use of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in wash-off cosmetic products comes into force in 2020.



Caterina Tani

EMEA reporter

**Related Articles**

- Regulation to restrict PFOA published
- Echa round-up
- In the news
- Sweden study looks at ecolabelling role in chemical restrictions
- Denmark raises awareness of fluorinated substances in outdoor wear
- Danish investigation finds fluorinated substances in cake packaging
- EU issues Regulation restricting D4, D5 in wash-off cosmetics

**Further Information:**

- EPA report
- EPA press release
- EPA press release (in Danish)
- Norwegian EPA press release (in Norwegian)

**US EPA broadens scope of PFAS detection method**

27 November 2018 / Exposure monitoring & measurement, PFCs, Test methods, United States

The US EPA has broadened the scope of a validated test method for detecting per- and poly-fluoroalkyl substances (PFASs) in drinking water to include four more compounds.

EPA Method 537.1 can detect the 'GenX' chemical, hexafluoropropylene oxide dimer acid (HFPO-DA), as well as:

- 11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS);
- 9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS); and
- 4,8-dioxa-3H-perfluorononanoic acid (ADONA).

These compounds bring the total number it can detect to 18.

PFASs can repel water, grease and oil and are used in a wide range of products, such as food packaging, cookware and clothing.

The EPA will host a free webinar on 28 November at 2:00 pm EDT, to provide further information on the method and its efforts to develop and validate analytical methods more generally.

On 14 November, the agency published its draft reference doses for Gen X chemicals as part of a broader effort to address PFASs.

**Related Articles**

- EPA releases draft toxicological profiles for two PFASs

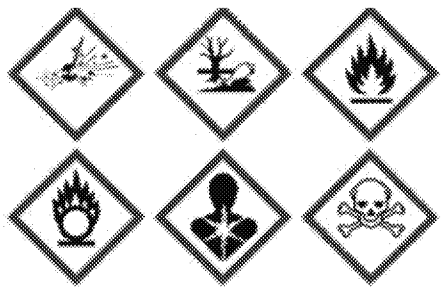
**Further Information:**

- Webinar registration

**Aise suggests review of GHS labelling hazard pictograms**

Need to address language barriers, comprehension issues

28 November 2018 / Classification, Cleaning products, GHS, Global, Labelling



An EU trade body has called for a review of pictograms included on the labels of chemical products so hazard warnings are conveyed more clearly to users.

According to soap and detergents group Aise the need has intensified as take-up of the UN's globally harmonized system of classification and labelling for chemicals (GHS) spreads among developing nations.

In a document shared with the Competent Authorities for REACH and CLP (Caracal) on 21-22 November, it said existing hazard pictograms should be assessed for "comprehensibility and suitability" in developing regions where exponentially growing populations of millions of consumers "with low literacy are exposed to hazardous chemicals".

The content of many labels of chemicals exported there "are not clearly understood", Aise said in its document addressed to the GHS Subcommittee of Experts. The trade body asked it to explore possibilities in its next two-year work programme.

GHS classification has been adopted to varying degrees in nearly all major countries, with more and more developing countries endorsing it. The standardised labels under GHS include hazard pictograms, signal words such as 'Danger', and hazard statements.

**Language concerns**

In addition, the trade body said in a joint submission with South African packaging body the RPMASA, the GHS subcommittee should consider replacing written statements such as 'Keep out of reach of children' with simple pictograms.

GHS currently has four types of precautionary statements covering prevention, response in case of accidental spillage or exposure, storage and disposal.

The current labelling requirements have led to information "overload" for the target audience which, as a result, often ignore it, the trade bodies said. They cited scientific studies confirming that graphical representations can be recognised more quickly.

The subcommittee should also consider the increased number of worldwide migrant workers using chemical products, where labels will be in a different language to their own, they said.

In July, the GHS subcommittee had agreed that precautionary pictograms could be included in the system, because they are already in use in a number of countries with high levels of understanding, Aise and the RPMASA added.

**Digital labels**

In another Caracal meeting document, Aise and the RPMASA proposed digitalisation of GHS hazard information to reflect the growth of online commerce through the use of tablets, mobile phones and computers.

This is creating new challenges in the way GHS label information is displayed, they said. For example, mobile devices can only accommodate reduced information while desktop computers can display it in full.

Digitalisation also offers "substantial opportunities" in terms of hazard communication, they said. These include:

- language and font size adapted to user needs;
- customised search options for key words can allow swift identification of most important information, such as the presence of sensitisers; and
- safe use instructions can be easily accommodated.

The groups proposed a "tiered approach" with the physical label on the product packaging containing the most relevant and critical elements, and more technical aspects of the GHS label given online.

Guidelines should be developed on how best to provide labelling information digitally, with consideration given to back-up solutions for users who are unable to connect to the internet, they said.

Earlier this month, the European Commission said it will explore ways to include endocrine disruption in the GHS classification.

Clelia Oziel

EMEA correspondent

**Related Articles**

- EU Commission eyes GHS classification for EDCs

**Further Information:**

- Aise on pictograms
- Aise on digitalisation
- GHS

**Business Guide to Safer Chemicals 2018: BPA could get canned**

A major can coatings producer has worked with other stakeholders to develop an alternative to bisphenol A-based epoxies

28 November 2018 / Bisphenols, Europe, Food & drink, Global, North America, REACH, SVHCs

**This article was first published in the *Business Guide to Safer Chemicals 2018*. Download your free copy of the guide for more in-depth, practical case studies that examine how companies are addressing the various chemical safety challenges they face.**

Bisphenol A (BPA)-based epoxies have become the default option in the coating of metal cans for food packaging over the last 60 years. About 80% of all metal packaging uses it, according to Thomas Mallen, technical director at Sherwin-Williams Packaging, which was known as Valspar until its acquisition by the coatings giant in June 2017.

BPA was put on the REACH candidate list of SVHCs due to its Category 1B reprotoxic properties in January 2017. Since 1 March 2018, all manufacturers, importers, or suppliers have had to classify and label mixtures containing BPA in this way.

In June 2017, Echa's Member State Committee also voted to identify BPA as a SVHC because of endocrine disrupting properties which cause probable serious effects to human health, giving rise to an equivalent level of concern to carcinogenic, mutagenic and reprotoxic (CMR) substances. Finally, the BPA entry was also updated to include endocrine disrupting properties causing adverse effects to the environment.

The substance has been banned from infant feeding bottles across the EU since June 2011, while three member states have banned it in other materials that come into contact with food intended for infants and children under three years. France has banned it in all food packaging, containers and utensils. It is still permitted in food contact materials, but with maximum migration limits that the European Food Safety Authority (Efsa) is re-evaluating.

Thus, there is a clear regulatory driver towards removing BPA from the epoxies used in can coatings. However, doing this without making compromises in terms of safety, performance and high speed application is a huge challenge, Mr Mallen says. There are a number, of reasons technical, regulatory and societal, why this is so.

First, BPA is used twice in the synthesis of these epoxies, so two steps are impacted by any changes. Secondly, a means has to be found to achieve a high molecular weight linear (not branched) polymer, in order to preserve the material's flexibility and ability to coat metals, and to ensure the same extremely low level of residuals that might migrate into the food.

"The replacement material must also be free of endocrine activity, to avoid regrettable substitutions," says Mr Mallen. "As we went through material discovery, we soon found that there is no one definition of what an endocrine-active material is, so that was a challenge too. And, once we had discovered one, it was important that society accepts that not all bisphenols are of concern. Many of them have no endocrine activity at all, but they are also not suitable for making polymers or monomers."

To get to the point where there are no concerns among stakeholders and society involved addressing several problems in the way regulatory agencies work, Mr Mallen continues. Food contact agencies generally focus on conventional safety and risk-based safety assessments, and are concerned with other toxicological endpoints than endocrine disruption. Chemical inventory regulatory agencies – like Echa with REACH or the US EPA with TSCA – require GLP-based procedures for human health and environment.

"Those have limitations in terms of fully utilising tests to look for other endpoints that may be of concern," Mr Mallen says. "And we recognise that there is a gap between testing for compliance and getting a more comprehensive answer that is sustainable in the long term."

In addressing this problem, Sherwin-Williams borrowed the concept of 'Safety by Design' from the pharmaceuticals industry. This is generally conceived as a funnel through which a large number of potential products is whittled down in stages through investigation of their regulatory characteristics until a much smaller number is left but with a much higher degree of confidence about the probability of success.

In its product development, Sherwin-Williams starts out with early material investigation, to find out if a product contains any chromophores or structural alerts that would give rise to concern later down the line. The next stage was "to impose on our R&D group endocrine testing for the components, as well as the materials that they make with those components – which is not a trivial issue".

Thus, many materials could be eliminated before the company needed to get further down in the process to toxicological assessment and migration testing, which are needed in order to do a risk assessment. "Eventually we started talking to regulators and others about these materials, submitting dossiers and notifications," Mr Mallen says.

Once Sherwin-Williams had a dataset it was comfortable with as a potential BPA replacement for can coating, it started reaching out to others to get their take on the dataset, its methods and anything missing to see what would convince them the materials were truly not endocrine active. They included:

- academic and state research bodies, such as Tufts University, Texas A&M University, UMass Amherst, Baylor College of Medicine and the UK's Food & Environment Research Agency (Fera);
- NGOs, such as ChemTrust, Breast Cancer Action, the Natural Resources Defense Council (NRDC), Clean Production Action (CPA), ChemSec and the Centre for Science in the Public Interest; and
- regulators, including the US Federal Drug Administration (FDA), Health Canada and France's French Agency for Food, Environmental and Occupational Health & Safety (Anses).

Tufts and Baylor have already published on the material Sherwin-Williams developed and the company has conducted a GreenScreen evaluation for them with CPA. It also engaged with ChemSec and was invited to put its new material on the Swedish NGO's Marketplace, which it saw as "a business-to-business opportunity for transparency," Mr Mallen says. "It really does help innovation to get noticed."

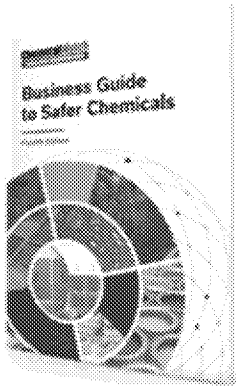
The product, ValPure 70, is described as a next-generation coating technology with epoxy-like performance. It is now being adopted in North and Central America and is being evaluated in Europe.

The monomer for this product, tetramethyl bisphenol F (TMBPF), had been registered under REACH by other companies in a substance information exchange (Sief) but only at low volumes and with little detail. Sherwin-Williams has therefore had to generate and send more information to the lead registrant (LR) to make the dossier acceptable at the highest volume level needed.

The epoxy was not pre-registered, so the company took that on itself, becoming LR for the Sief which others have joined. It is now going through the same process of testing and submission to Echa.

"One of the key things for us to develop trust between the stakeholders in society was to be transparent and put all the material from us and others on a dedicated website," Mr Mallen says. "We feel like we met the challenge, although of course the journey continues."

How are companies in the chemicals industry addressing the complex and practical challenges of making safer chemicals?




**The *Business Guide to Safer Chemicals*, now in its fourth year, brings together a series of in-depth, practical case studies that examine how companies are addressing the various chemical safety challenges they face.**

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