Frequently Asked Questions About Substances of Very High Concern For Manufacturers and Downstream Users

Q. What is a Substance of Very High Concern (SVHC)?

SVHC is a regulatory designation made about certain chemicals under chemical regulations in the European Union (EU), or REACH (EC 1907/2006).

It is important to note that identification of a substance as a SVHC is not a restriction of its marketing and use in Europe. It also does not mean that the substance has been found to pose a risk to human health or the environment. In fact, the process for determining SVHC is not allowed to consider the exposure or risk of nominated compounds.

Designation as SVHC is a means to communicate prioritization of a chemical for consideration for further assessment using a process called evaluation of Risk Management Options, i.e. "authorisation" or restriction under REACH.

Designation as an SVHC does impart some obligation to communicate with customers on companies that manufacture, import or use the SVHC compounds in the European Union (EU), whether on its own, or depending on its concentration, in preparations or articles. Questions about these obligations are answered below in this FAQ document.

Q. What is REACH?

REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical substances.

REACH entered into force on 1 June 2007 and its provisions are being phased-in over 11 years. Additional information about REACH is available on the European Chemicals Agency (ECHA) website

Q. Who decides if a compound is SVHC?

Compounds can be nominated for SVHC by either ECHA or a Member State. After ECHA processes the nomination reports and posts them for public comments, the final decision to designate a compound as SVHC is taken by the European Member State Committee (MsC), which includes representatives from each of the EU countries.

Q. Who has responsibility for implementing and enforcing REACH and the requirements of SVHC?

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The European Chemicals Agency (ECHA) is responsible for implementing European Community Regulation on chemicals and their safe use (EC 1907/2006).

Q. Which alkylphenols (AP) and alkylphenol ethoxylates (APEs) have been designated as SVHC?

The following AP/APE compounds have been designated as SVHC; however none of them have been found to pose a risk in the EU or elsewhere:

- **4-(1,1,3,3-tetramethylbutyl)phenol** [covering well-defined substances and UVCB substances, polymers and homologues] , also described at para-tert-octylphenol (OP)- Effective December 19, 2011
- **Nonylphenol, branched and linear (NP),** also described broadly as "substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof" – Effective December 19, 2012
- **4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated - Covering Well-defined Substances and UVCB Substances, Polymers and Homologues,** more commonly known as octylphenol ethoxylates (OPE) – Effective December 19, 2012.

Q. Have any other AP/APE compounds been nominated for SVHC?

4-Nonylphenol, branched and linear, ethoxylated (NPE) was nominated by the German authorities on April 3, 2013. The public comment period for this nomination ended April 18, 2013.

The Annex XV Report nominating NPE for SVHC described this group of polymers very broadly as: "4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]".

Q. Is it true that there was no concern for human health effects expressed in the reports that nominated OP, OPE, NP, and NPE as SVHC?

It is true that none of the Annex XV Reports that nominated AP/APE compounds as SVHC raised any concern with the human health effects of these compounds. None of these compounds are carcinogenic, mutagenic or reproductive toxicants.

Q. OP and NP are <u>not</u> carcinogenic, mutagenic, reproductive toxicants, nor are they persistent or bioaccumulative, so why were they nominated for SVHC?

The nominations for OP and NP were based on the argument that these substances have weak estrogenic activity and alleged these compounds could have "probable serious" effects in fish but not to human health.

Q. Were there objections to the nominations of OP and NP as SVHCs?

The Alkylphenols & Ethoxylates Research Council (APERC), a North American based group, and the European Council for Alkylphenols and Derivatives (CEPAD) jointly submitted comments to ECHA objecting to the proposals to identify OP and NP as SVHC. The primary basis for objection was that neither of these compounds meet the criteria for SVHC compounds, which are listed under Article 57 of REACH.

Neither NP nor OP are CMR, PBT or vPvB compounds, which are described under Article 57 (a) – (e) of REACH.

Article 57(f) gives the following criteria for SVHC compounds: "compounds such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of <u>probable serious effects</u> to human health or the environment <u>which give rise to an equivalent level of concern</u> to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article" (emphasis added).

Comments submitted by APERC and CEPAD pointed out that these alkylphenols have only weak estrogenic activity that is one thousand to one million fold less potent than 17ß-estradiol (E2) and 17α-ethynylestradiol (EE2). In addition, any adverse effects caused by NP or OP are not "clearly endocrine mediated", but rather are indicative of general toxicity possibly coupled with very weak estrogenic activity. While these compounds are toxic to fish and other aquatic species, their effects are clearly not comparable to actual estrogens. Also, just because a compound is estrogenically active

does not mean it is going to cause "probable serious" effects in fish or other aquatic species.

In the case of NP/NPE and OP/OPE, environmental concentrations in EU waters are generally below levels of concern for any type of adverse effects in fish or other aquatic organisms. Thus, there is no evidence that they cause probable serious effects to human health or the environment, which give rise to an equivalent level of concern under Article 57. The process for determining SVHC compounds specifically prohibits consideration of occurrence and exposure in the environment. This type of information is applied during the "authorisation" process under REACH.

Q. NPE and OPE are not, carcinogenic, mutagenic, reproductive toxicants, persistent, bioaccumulative OR estrogenically active so why were they nominated as SVHCs?

NPE and OPE are polymeric surfactants, which are not CMR, PBT or vPvB. The commercial polymers are not estrogenically active. NPE and OPE were nominated as SVHC primarily on the basis that NP and OP, which have been designated SVHC, occur during the degradation of their ethoxylates in the environment. In other words, the polymers are considered an "environmental source" of these SVHC compounds.

CEPAD and APERC continue to disagree with the SVHC determinations for NP and OP; however even recognizing this designation, the assumption that degradation of a polymer to an intermediate that is designated as SVHC also warrants designation of the polymer as SVHC is inconsistent with the requirements and intention of Article 57. The criteria under Article 57 list specific hazard-based properties that should apply to the SVHC candidates for authorisation and there is no inference under Article 57, or elsewhere in the REACH regulations, that SVHC candidate chemicals for authorisation under Annex XIV should be anything other than chemicals that meet one or more of those hazard criteria.

Q. When will OP, NP and OPE move to the Risk Management Option (RMO) process under REACH?

There is no requirement that ECHA move a SVHC compound to the RMO stage within a particular timeframe.

It should be recognized that use as a chemical intermediate is generally exempt from the authorisation process under REACH. All major uses of OP and NP are intermediate uses

that involve additional chemical synthesis, such as its use as a monomer in resin production or as a reactant in ethoxylation for the production of surfactants. The dispersive uses of NP/NPE already fall under an existing market and use restriction in the EU and the major producers have already defined such uses as uses advised against in the EU. We therefore believe that no further RMO are needed for these substances as uses with direct releases to the environment should no longer occur.

Q. What happens if a compound moves to the authorisation process under REACH?

If a compound reaches the authorisation stage under REACH, it will be eventually listed on REACH Annex XIV. Once the sunset date has passed for an Annex XIV substance, only uses which have been specifically 'authorised', or which do not require authorisation (i.e., are exempt), will be allowed.

Q. What does the addition of a compound to the SVHC list mean for my company? *

Although REACH is only applicable within the European Union, SVHC status will also trigger obligations for certain non-EU companies to communicate with the EU downstream value chain. Communication obligations pertain to companies that import SVHC substances, or mixtures that contain a SVHC compound at concentrations greater than 0.1 % by weight, into the EU. Therefore, the residual level of a SVHC substance must be determined in downstream products to ascertain whether or not reporting requirements exist.

In addition, all companies producing or importing mixtures containing an SVHC in the EU have to provide a Safety Data Sheet that identifies it above 0.1% by weight. Since NP and OP are already classified under the Classification and Labelling Directive (CLD) for hazard endpoints, e.g., corrosivity and environmental toxicity, this does not represent a new requirement for these compounds.

Producers or importers of articles have to notify ECHA if residual SVHC compounds are present in the final article above 0.1% by weight.

There are no legal obligations for communication or otherwise in cases where an SVHC is contained <0.1% in mixtures or in articles.

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** The information in this FAQ document is provided as guidance regarding the requirements for companies impacted by the designation of as a SVHC. It is not intended as regulatory or legal advice. All companies should review and comply with relevant regional, national and local regulations.*

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