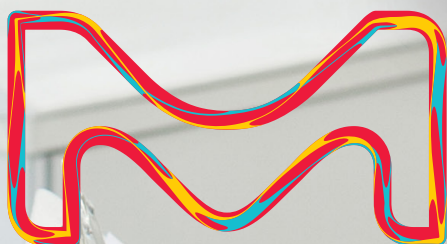
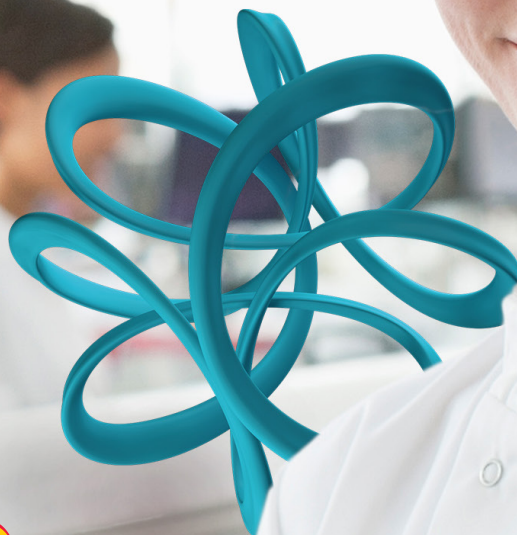


Detergents REACH update

Inclusion of Alkylphenol Ethoxylates
in Annex XIV



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REACH Update – Inclusion of Alkylphenol Ethoxylates in Annex XIV

Merck is aware of the current concerns among our customers and the wider market regarding the inclusion of octylphenol ethoxylates (OPE), such as Triton X-100, and nonylphenol ethoxylates (NPE) in the European Authorisation list (Annex XIV) of REACH.

For those unfamiliar with this regulatory system, REACH stands for the **R**egistration, **E**valuation, **A**uthorisation and **R**estrictions of **C**hemicals, and addresses the production, import and use of chemical substances and their potential impacts on human health and the environment. REACH affects European manufacturers, importers and downstream users as well as non-European manufacturers exporting their products into the EU.

OPE and NPE substances were included in REACH Annex XIV on June 14, 2017. The REACH Annex XIV sunset date is **January 4, 2021**. After this date, OPE and NPE products cannot be used, unless authorization was granted by the authorities or the intended use is exempted from authorization. Important exemptions are: the use in scientific research and development, or the use as an intermediate. An application for authorization is anticipated to be costly, and is granted for a limited period (approximately 7-12 years), but can be renewed. The application deadline for OPE and NPE is July 4, 2019. The authorization process places significant emphasis on the substitution of affected substances.

While OPE and NPE availability is not affected in the short term, the development of new products using these substances is **NOT** advisable due to the reasons outlined above. Therefore, customers are encouraged to evaluate alternative detergents in their development process. **Merck does not intend to apply for the authorization of customers' uses of these substances. It is the responsibility of our customers to check the necessity of application for authorization of their intended uses.**

Options for our customers include:

1. **Determine if the OPE or NPE is used in a scientific research and development (SRD) application. SRD applications are exempt from authorization requirements. This exemption applies to analytical activities using in vitro diagnostic (IVD) and medical devices at a laboratory scale. To determine if the exemption applies, carefully review the ECHA Q&As on: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation>**
 - Does the exemption for the use of Annex XIV substances in scientific research and development under Article 56(3) REACH also apply to analytical activities such as monitoring and quality control? **(ECHA ID 0585)**
 - Article 56 (3) of REACH exempts from the authorization requirement the use of a substance in scientific research and development (SRD). Does this exemption also cover the life-cycle steps (such as formulation) preceding the end-use in SRD? **(ECHA ID 1030)**
 - Does the exemption for the use of Annex XIV substances in scientific research and development under Article 56(3) REACH also apply to analytical activities using in vitro diagnostic (IVD) medical devices (as defined in Directive 98/79/EC) at a laboratory scale? **(ECHA ID 1442)**
 - Does the exemption for the use of Annex XIV substances in scientific research and development under Article 56(3) REACH also apply to the use of an Annex XIV substance in upstream life-cycle stages to produce IVD medical devices (e.g. reagents, calibrator, control material or kits) if the Annex XIV substance is not incorporated into the in vitro diagnostic (IVD) device? **(ECHA ID 1443)**

2. **Submit your own application for authorization. This could be as an individual applicant, or as part of a consortium.**
3. **Identify and validate alternative products which require no authorization, and are not on the candidate list or Annex XIV already. We offer an extensive list of alternative detergents and surfactants that may replace NPE and OPE products in your process, and can be checked for suitability. These replacements are grouped under the four main categories listed below, and in Tables 1 and 2 that follow.**
 - **ECOSURF™ EH Series** - Specialty Ethoxylated Surfactants: Excellent wetting and hard surface cleaning, favorable handling and formulating properties, low odor, readily biodegradable, very low aquatic toxicity
 - **ECOSURF™ SA Series** - Specialty Ethoxylated Surfactants: Improved handling (no aqueous gel range, lower pour point), fast dissolution time, low odor, good detergency, biorenewable based, hydrophobe, readily biodegradable
 - **TERGITOL™ 15-S Series** - Secondary Alcohol Ethoxylates: Excellent wetting, fast dissolution time, fast dynamic surface tension reduction, low odor, good detergency, favorable handling properties, readily biodegradable
 - **TERGITOL™ TMN Series** - Branched Secondary Alcohol Ethoxylates: Unique combination of superior emulsification, wetting and detergency, very low surface tension, excellent formulating and handling properties

Table 1: OPE products are identified in red text with potential replacement products listed below. The closest matching replacement product is highlighted in bold.

Product Name	Contains Alkylphenol Ethoxylates / Type	Moles of EO	Cloud Point (1%) °C	HLB	Pour Point °C	Readily Biodegradable (OECD 301F)	Cat. No.
TRITON™ X-100	Yes / OPE	9.5	66	13.4	1		X100
ECOSURF™ EH-9	No	Proprietary	61	12.5	12	•	STS0006
ECOSURF™ EH-9 (90%)	No	Proprietary	61	12.5	-5	•	STS0012
ECOSURF™ SA-9	No	Proprietary	57	11.1	4	•	STS0007
TERGITOL™ 15-S-9	No	9	60	13.3	9	•	15S9
TERGITOL™ TMN-100X (90%)	No	9	65	14	-6		STS0004
TRITON™ X-102	Yes / OPE	12	88	14.4	13		X102
ECOSURF™ EH-9	No	Proprietary	61	12.5	12	•	STS0006
ECOSURF™ EH-9 (90%)	No	Proprietary	61	12.5	-5	•	STS0012
TERGITOL™ TMN-10 (90%)	No	11	76	14.1	-19		86454
TRITON™ X-114	Yes / OPE	7.5	25	12.3	-14		X114
TERGITOL™ 15-S-7	No	7	37	12.1	1	•	15S7
TERGITOL™ TMN-6 (90%)	No	8	36	13.1	< -40		86453
TRITON™ X-165 (70%)	Yes / OPE	16	>100	15.5	22		X165
TERGITOL™ 15-S-15	No	15	>100	15.4	29	•	STS0014
TRITON™ X-305 (70%)	Yes / OPE	30	>100	17.3	-7		X305
TERGITOL™ 15-S-30	No	31	>100	17.4	39	•	STS0001
TERGITOL™ 15-S-40	No	41	>100	18	43	•	STS0002
TERGITOL™ 15-S-40 (70%)	No	41	>100	18	5	•	STS0003
TRITON™ X-405 (70%)	Yes / OPE	35	>100	17.6	-6		X405
TERGITOL™ 15-S-30	No	31	>100	17.4	39	•	STS0001
TERGITOL™ 15-S-40	No	41	>100	18	43	•	STS0002
TERGITOL™ 15-S-40 (70%)	No	41	>100	18	5	•	STS0003
TRITON™ X-705 (70%)	Yes / OPE	55	>100	18.4	2		not available
TERGITOL™ 15-S-40	No	41	>100	18	43	•	STS0002
TERGITOL™ 15-S-40 (70%)	No	41	>100	18	5	•	STS0003

Table 2: NPE products are identified in red text with potential replacement products listed below. The closest matching replacement product is highlighted in bold.

Product Name	Contains Alkylphenol Ethoxylates / Type	Moles of EO	Cloud Point (1%) °C	HLB	Pour Point °C	Readily Biodegradable (OECD 301F)	Cat. No.
TERGITOL™ NP-9	Yes / NPE	9	54	12.9	-1		NP9
ECOSURF™ EH-9	No	Proprietary	61	12.5	12	•	STS0006
ECOSURF™ EH-9 (90%)	No	Proprietary	61	12.5	-5	•	STS0012
ECOSURF™ SA-9	No	Proprietary	57	11.1	4	•	STS0007
TERGITOL™ 15-S-9	No	9	60	13.3	9	•	15S9
TERGITOL™ TMN-6 (90%)	No	8	36	13.1	< -40		86453
TERGITOL™ TMN-100X (90%)	No	9	65	14	-6		STS0004
TERGITOL™ NP-10	Yes / NPE	10	63	13.2	6		NP10
ECOSURF™ EH-9	No	Proprietary	61	12.5	12	•	STS0006
ECOSURF™ EH-9 (90%)	No	Proprietary	61	12.5	-5	•	STS0012
ECOSURF™ SA-9	No	Proprietary	57	11.1	4	•	STS0007
TERGITOL™ 15-S-9	No	9	60	13.3	9	•	15S9
TERGITOL™ TMN-100X (90%)	No	9	65	14	-6		STS0004
TERGITOL™ NP-40 (70%)	Yes / NPE	40	>100	17.8	2		not available
TERGITOL™ 15-S-40 (70%)	No	41	>100	18	5	•	STS0003

The information contained in this letter expresses only the intention of the sender and does not constitute a binding obligation. While the information has been provided to the best of our knowledge, no representations or warranties are made with regard to its completeness or accuracy. Except for any mandatory statutory liability, no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information unless the damages were caused by grossly negligent or willful behavior. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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