



159 Swanson Road, Boxborough, MA 01719-1304
Telephone: 978-263-1400 • 800-257-3872 • Fax: 978-264-0292
Email: sales@setra.com

**DECLARATION OF COMPLIANCE
TO EU REACH REGULATIONS**

Setra Systems Inc. complies with EU REACH REGULATION no 1907/2006 on the **R**egistration, **E**valuation, **A**uthorization, and restriction of **C**hemicals for Setra products.

Reference Sites:

Summary of the obligations linked to the Candidate List:

<http://echa.europa.eu/candidate-list-obligations>

Official REACH requirement:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF>

REACH Official Site:

<http://echa.europa.eu/web/guest/regulations/reach>

REACH Guidance Fact Sheet:

http://echa.europa.eu/documents/10162/17224/articles_fact_sheet_en.pdf

Requirements:

According to REACH, a producer or importer needs to submit a registration (Article 7.1) or notification (Article 7.2) to ECHA (European Chemical Agency), and provide the recipient sufficient information (Article 33) if:

Article 7.1:

- (a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year;
- (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Article 7.2:

- (a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year;
- (b) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w).

Article 33 states that any supplier of an article which contains a SVHC (Substance of Very High Concern) above 0.1% shall provide the recipient of the article sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

Setra's feedback on compliance requirements in REACH Articles 7.1, 7.2, and 33:

- **SHIPMENTS:** Setra's shipments to Europe have not exceeded one tonne per year for any of the chemicals listed in the EU REACH regulations.
- **SUBSTANCES INTENDED TO BE RELEASED:** In review of the REACH standards and the "REACH Guidance Fact Sheet" (Requirements for substances in articles), Setra's products do not intend to release the identified substances identified in REACH (Article 57) under normal or reasonably foreseeable conditions of use.
- **SUBSTANCES OF VERY HIGH CONCERN (SVHC):**
 - Candidate list of SVHC chemicals, released on 1/12/2017
http://www.echa.europa.eu/chem_data/candidate_list_table_en.asp



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Substance Name	Date of inclusion
4,4'-isopropylidenediphenol	12/1/2017
4-heptylphenol, branched and linear	12/1/2017
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	12/1/2017
p-(1,1-dimethylpropyl)phenol	12/1/2017
Benzo[def]chrysene (Benzo[a]pyrene), Benzo[def]chrysene(Benzo[a]pyrene)	6/20/2016
1,3-propanesultone	12/17/2015
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	12/17/2015
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	12/17/2015
Nitrobenzene	12/17/2015
Perfluorononan-1-oic-acid and its sodium and ammonium salts	12/17/2015
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters	6/15/2015
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2]	6/15/2015
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	12/17/2014
reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	12/17/2014
Cadmium fluoride	12/17/2014
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	12/17/2014
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	12/17/2014
Cadmium sulphate	12/17/2014
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	6/16/2014
Sodium perborate; perboric acid, sodium salt	6/16/2014
Sodium peroxometaborate	6/16/2014
Cadmium chloride	6/16/2014
Cadmium sulphide	12/16/2013
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	12/16/2013
Dihexyl phthalate	12/16/2013
Imidazolidine-2-thione, (2-imidazoline-2-thiol)	12/16/2013
Trixylyl phosphate	12/16/2013
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	12/16/2013
Lead di(acetate)	12/16/2013
Cadmium	6/20/2013
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]	6/20/2013
Ammonium pentadecafluorooctanoate (APFO)	6/20/2013
Pentadecafluorooctanoic acid (PFOA)	6/20/2013
Dipentyl phthalate (DPP)	6/20/2013
Cadmium oxide	6/20/2013
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	12/19/2012



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6-methoxy-m-toluidine (p-cresidine)	12/19/2012
Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	12/19/2012
Pyrochlore, antimony lead yellow	12/19/2012
Henicosaflluoroundecanoic acid	12/19/2012
4-Aminoazobenzene	12/19/2012
Silicic acid, lead salt	12/19/2012
Lead titanium zirconium oxide	12/19/2012
Lead monoxide (lead oxide)	12/19/2012
o-Toluidine	12/19/2012
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	12/19/2012
Dibutyltin dichloride (DBTC)	12/19/2012
Lead bis(tetrafluoroborate)	12/19/2012
Lead dinitrate	12/19/2012
Silicic acid (H ₂ Si ₂ O ₅), barium salt (1:1), lead-doped [with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD) The substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]	12/19/2012
Trilead bis(carbonate)dihydroxide	12/19/2012
4,4'-methylenedi-o-toluidine	12/19/2012
Diethyl sulphate	12/19/2012
Dimethyl sulphate	12/19/2012
N,N-dimethylformamide	12/19/2012
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	12/19/2012
4-Nonylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	12/19/2012
Furan	12/19/2012
Lead oxide sulfate	12/19/2012
Lead titanium trioxide	12/19/2012
Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)	12/19/2012
Dinoseb (6-sec-butyl-2,4-dinitrophenol)	12/19/2012
1,2-Diethoxyethane	12/19/2012
N-methylacetamide	12/19/2012
Tetralead trioxide sulphate	12/19/2012
Acetic acid, lead salt, basic	12/19/2012
[Phthalato(2-)]dioxotrilead	12/19/2012
Tetraethyllead	12/19/2012
N-pentyl-isopentylphthalate	12/19/2012
Pentalead tetraoxide sulphate	12/19/2012
Heptacosaflluorotetradecanoic acid	12/19/2012
Tricosaflluorododecanoic acid	12/19/2012
1-bromopropane (n-propyl bromide)	12/19/2012
Dioxobis(stearato)trilead	12/19/2012
Pentacosaflluorotridecanoic acid	12/19/2012
Methoxyacetic acid	12/19/2012



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Methyloxirane (Propylene oxide)	12/19/2012
Trilead dioxide phosphonate	12/19/2012
o-aminoazotoluene	12/19/2012
4-methyl-m-phenylenediamine (toluene-2,4-diamine)	12/19/2012
Diisopentylphthalate	12/19/2012
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	12/19/2012
Biphenyl-4-ylamine	12/19/2012
Fatty acids, C16-18, lead salts	12/19/2012
Orange lead (lead tetroxide)	12/19/2012
4,4'-oxydianiline and its salts	12/19/2012
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	12/19/2012
Sulfurous acid, lead salt, dibasic	12/19/2012
Lead cyanamidate	12/19/2012
a,a-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	6/18/2012
[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	6/18/2012
N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	6/18/2012
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (I ² -TGIC)	6/18/2012
Diboron trioxide	6/18/2012
1,2-bis(2-methoxyethoxy)ethane (TEGDME; trigyme)	6/18/2012
Formamide	6/18/2012
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	6/18/2012
Lead(II) bis(methanesulfonate)	6/18/2012
1,2-dimethoxyethane	6/18/2012
[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	6/18/2012
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	6/18/2012
4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	6/18/2012
Phenolphthalein	12/19/2011
N,N-dimethylacetamide	12/19/2011
4-(1,1,3,3-tetramethylbutyl)phenol	12/19/2011
Lead diazide, Lead azide	12/19/2011
Lead dipicrate	12/19/2011
1,2-dichloroethane	12/19/2011
Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (Åµm) c) alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+MgO+BaO) content less or equal to 18% by weight	12/19/2011
Calcium arsenate	12/19/2011
Dichromium tris(chromate)	12/19/2011
2-Methoxyaniline, o-Anisidine	12/19/2011
Pentazinc chromate octahydroxide	12/19/2011



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Arsenic acid	12/19/2011
Potassium hydroxyoctaoxodizincatedichromate	12/19/2011
Formaldehyde, oligomeric reaction products with aniline	12/19/2011
Lead styphnate	12/19/2011
Bis(2-methoxyethyl) phthalate	12/19/2011
Trilead diarsenate	12/19/2011
Bis(2-methoxyethyl) ether	12/19/2011
2,2'-dichloro-4,4'-methylenedianiline	12/19/2011
Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (Åµm). c) alkaline oxide and alkali earth oxide (Na ₂ O+K ₂ O+CaO+MgO+BaO) content less or equal to 18% by weight	12/19/2011
Cobalt dichloride	6/20/2011 10/28/2008
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	6/20/2011
Strontium chromate	6/20/2011
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	6/20/2011
1-Methyl-2-pyrrolidone	6/20/2011
1,2,3-Trichloropropane	6/20/2011
2-Ethoxyethyl acetate	6/20/2011
Hydrazine	6/20/2011
Cobalt(II) diacetate	12/15/2010
2-Ethoxyethanol	12/15/2010
Cobalt(II) sulphate	12/15/2010
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	12/15/2010
2-Methoxyethanol	12/15/2010
Chromium trioxide	12/15/2010
Cobalt(II) carbonate	12/15/2010
Cobalt(II) dinitrate	12/15/2010
Trichloroethylene	6/18/2010
Potassium dichromate	6/18/2010
Tetraboron disodium heptaoxide, hydrate	6/18/2010
Boric acid	6/18/2010
Ammonium dichromate	6/18/2010
Sodium chromate	6/18/2010
Disodium tetraborate, anhydrous	6/18/2010
Potassium chromate	6/18/2010
Acrylamide	3/30/2010
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1/13/2010
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	1/13/2010
2,4-Dinitrotoluene	1/13/2010
Anthracene oil	1/13/2010
Anthracene oil, anthracene paste, anthracene fraction	1/13/2010



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Anthracene oil, anthracene-low	1/13/2010
Diisobutyl phthalate	1/13/2010
Tris(2-chloroethyl)phosphate	1/13/2010
Lead chromate	1/13/2010
Anthracene oil, anthracene paste	1/13/2010
Pitch, coal tar, high temp.	1/13/2010
Anthracene oil, anthracene paste, distn. lights	1/13/2010
Lead hydrogen arsenate	10/28/2008
Benzyl butyl phthalate (BBP)	10/28/2008
Bis (2-ethylhexyl)phthalate (DEHP)	10/28/2008
Bis(tributyltin)oxide (TBTO)	10/28/2008
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	10/28/2008
Diarsenic trioxide	10/28/2008
Triethyl arsenate	10/28/2008
Diarsenic pentaoxide	10/28/2008
Sodium dichromate	10/28/2008
Dibutyl phthalate (DBP)	10/28/2008
4,4'- Diaminodiphenylmethane (MDA)	10/28/2008
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	10/28/2008
Anthracene	10/28/2008
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	10/28/2008

- Article 7.2 – Setra does not exceed one tonne per year for the SVHC.
- Article 33 – Setra is reviewing permanently the latest ECHA list of SVHC to confirm Setra’s products do not contain these substances in levels above a concentration of 0.1% weight by weight of product. Setra will provide immediately any updated changes to Setra customers when required for safe use of products and/or when amendments to the SVHC candidate list occur.

As a result, Setra meets the requirements in EU REACH.

Title: Quality Manager

Date: February 8, 2017

Signature: 