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# MKS REACH Regulation Position Statement Revision D – February 2014

### **REACH Background:**

In late 2006, the European Union (**EU**) enacted a comprehensive regulatory framework for the  $\underline{\mathbf{R}}$  egistration,  $\underline{\mathbf{E}}$  valuation and  $\underline{\mathbf{A}}$  uthorization of  $\underline{\mathbf{Ch}}$  emicals (**REACH**). The REACH Regulation (O.J. L 396/1, as amended) officially entered into force on June 1, 2007, although most of the operative provisions have been and are being phased in over a series of years.

Because REACH is an EU regulation rather than a directive, it is directly applicable to private parties and does not need to be separately implemented through EU Member States' legislation. EU Member States are, however, responsible for enforcement of REACH requirements.

REACH places a general obligation on all EU manufacturers and importers of <u>substances</u> to register each substance that is manufactured or imported in quantities of 1 metric ton or more per year with the European Chemicals Agency (ECHA). This includes registration of substances that are intended to be released from <u>articles</u> (e.g., manufactured goods such as finished products, parts and components) during normal and reasonably foreseeable conditions of use. Article producers and importers may also have a notification obligation to the ECHA with respect to certain "substances of very high concern". Information requirements may apply to the EU supplier of articles containing such substances of very high concern. "Downstream users" of substances must ensure that they implement applicable safety measures and fulfill certain administrative requirements. The ECHA manages the registration and information gathering process, with the aim of identifying priority substances that may pose a risk to human health or the environment. Authorization will be required for the use and placing on the market of all substances identified as causing probable serious harms to human health or the environment, and the European Commission may place an EU-wide restriction (ban) on certain substances.

#### **MKS Compliance Position:**

#### Substances intended to be released:

Subject to certain conditions, Article 7.1 of REACH requires that any EU producer or importer of articles shall submit a registration to the ECHA for any substances that meet both of the following criteria: (i) are intended to be released from those articles during normal and reasonably foreseeable conditions of use and (ii) are present in those articles in quantities totaling over 1 metric ton per producer/importer per year.

Based on our internal assessments using available ECHA guidance and in consultation with outside regulatory attorneys, we believe that none of our products contain substances that are intended to be released under normal and reasonably foreseeable conditions of use. Therefore, we do not believe that MKS has any direct registration obligation under Article 7.1 of REACH.



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#### Substances of very high concern:

Subject to certain conditions, Article 7.2 of REACH requires that any EU producer or importer of articles shall submit a notification to the ECHA for any substances that meet all of the following criteria: (i) are listed by the ECHA on a public "candidate list" of "substances of very high concern" (**SVHC**s), (ii) are present in those articles in quantities totaling over 1 metric ton per producer/importer per year and (iii) are present in those articles above a concentration of 0.1% weight by weight (w/w). This notification requirement became effective in June 2011 and certain exceptions apply. Based on a review of the current "candidate list" of SVHCs, we do not believe that MKS has any notification obligations under Article 7.2 of REACH. We are closely monitoring these issues and will continue to adapt our compliance strategy to known changes in the SVHC list – as they occur.

Article 33 of REACH requires that any EU supplier of articles containing SVHCs in a concentration above 0.1% weight (w/w) must provide the recipient with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the SVHC(s). Such suppliers must also respond to consumer requests for information about SVHCs. In the future, it is possible that MKS may have information obligations under Article 33 of REACH, depending on changes to the "candidate list". We are closely monitoring these issues and will continue to adapt our compliance strategy to known requirements when applicable.

#### Downstream user and other requirements:

Subject to certain conditions, Title V and certain other provisions of REACH require that any EU "downstream user" of substances or preparations that are mixtures of substances (*e.g.*, process materials such as solvents, pastes, solders, greases, liquids, inks, paints, gases) shall comply with risk control measures in safety data sheets or other risk management information received, as well as pass this information up and down the supply chain (where applicable) and fulfill recordkeeping requirements. In certain cases, "downstream users" must prepare chemical safety reports and/or report to the ECHA. Based on our internal assessments using available ECHA guidance and in consultation with outside regulatory attorneys, we do not believe that MKS is required to prepare any chemical safety reports. We will continue to comply with all "downstream user" requirements to the extent applicable to our EU operations.

Certain other requirements under REACH apply to EU entities that manufacture, import or place on the market substances, either on their own or in preparations, in quantities of 1 metric ton or more per year. Based on our internal assessments using available ECHA guidance and in consultation with outside regulatory attorneys, we believe that none of our EU operations manufacture, import or place on the market substances in such quantities. Therefore, we do not believe that MKS has any direct obligations applicable to such entities under REACH.



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## Risks Beyond MKS' Control:

- 1. Even where MKS is not subject to direct obligations under REACH, certain of its EU customers or business partners may be, depending on their specific operations and practices. This position statement does not address all of the REACH considerations that may be relevant to such parties in light of their particular circumstances and is not intended as REACH advice.
- 2. This position statement is based on current provisions of REACH, as amended and available ECHA guidance, all of which are subject to change, possibly with retroactive effect. The ECHA, any EU Member State or any other regulatory or enforcement authority may disagree with our assessments. Because REACH is still relatively new, is subject to further revision, may be enforced inconsistently within and among EU Member States and for other similar reasons, it is impossible to predict with certainty all requirements under REACH.
- 3. It is possible that certain process materials, parts or components may become unavailable due to REACH. If MKS needs to make process or design changes due to such unavailability, then there may be an impact on our products and/or delays in shipment. We intend to continue to serve the EU and other markets in full compliance with applicable laws and expect our suppliers and customers to be partners in that effort.

#### **Disclaimer:**

THIS POSITION STATEMENT IS FOR INFORMATIONAL PURPOSES ONLY, DOES NOT CONSTITUTE A LEGAL REPRESENTATION AND DOES NOT CREATE OR CONFIRM THE EXISTENCE OF ANY RIGHTS, LIABILITIES OR OBLIGATIONS OF MKS, ITS AFFILIATES, ANY OF THEIR RESPECTIVE CUSTOMERS OR ANY OTHER PERSON. THE SALE OF MKS PRODUCTS SHALL BE GOVERNED EXCLUSIVELY BY THE TERMS AND CONDITIONS SET FORTH IN THE APPLICABLE MKS SALE AGREEMENT.

MKS' assessments contained in this position statement are solely MKS' opinion. MKS does not guarantee the accuracy or completeness of its evaluation and neither MKS' customers nor any other party may rely on this position statement. The information contained herein is based on information MKS has obtained as of the date indicated at the top of this position statement. MKS does not have any obligation to update this position statement. Any MKS customer or other person needing information or guidance about REACH should seek advice of legal counsel