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General Background on the TSCA Low Volume Exemption

The Low Volume Exemption ("LVE") offers the possible advantage of earlier market entry in that it is normally reviewed in a shorter timeframe than a premanufacture notification ("PMN") under the Toxic Substances Control Act ("TSCA"). Under TSCA section 5, manufactures and importers of a new chemical substance for a non-exempt commercial purpose must submit a notification in advance of this activity to the Environmental Protection Agency (EPA). A potential option to making a full PMN submission is to submit a LVE application instead. The conditions for an LVE are listed at 40 C.F.R. § 723.50 and can be summarized as follows:

- The LVE is available only for chemicals manufactured at 10,000 kg/year or less. The 12-month production volume period is measured from the end of the LVE review.
- Description of categories of use.
- Applications are subject by rule to a 30-day review, although currently the process often takes longer.
- Lower user fees are available for an LVE submission.
- An LVE holder is bound to the conditions described in the LVE application with respect to use, site of manufacture, exposure and release controls, specified worker protection; and physical form. An LVE holder also is bound to importation only if this condition is specified in the application.
- Material changes in any of the conditions listed above can trigger the need for a new LVE application.
- LVE submitters must certify their knowledge and willingness to comply with LVE terms and their intent to manufacture the substance within one year of expiration of the review period.

LVE applications must include information similar to that required in a PMN submission, including manufacturer identity, a current chemical abstracts (CA) name, impurities, known synonyms or trade names, and byproducts. The application must specify the 12-month production volume, and a submitter will be bound to a lower volume if the corresponding binding box is marked, otherwise 10,000 kg/year will be assumed. Other notable information elements are a description of categories of use, readily known or available information on worker exposure and environmental releases (if not supplied, EPA develops its own estimates), and any test data (including physical/chemical data) in submitter's possession or control

concerning the effect(s) of the substance on health or the environment must be submitted with the exemption.

EPA can deny an LVE application if it determines that the substance fails to meet the terms of the exemption or for lack of sufficient information. The exemption also can be revoked for failure to meet the LVE's terms and conditions.

A consideration which can make LVE status challenging from a customer standpoint is that an LVE substance is not listed as an "existing" chemical substance listed on the TSCA Chemical Substances Inventory. Moreover, the right to manufacture is limited to the LVE holder (which includes a toll manufacturer arrangement), although EPA can approve up several LVEs per chemical substance. Most critically, the conditions of approval must be followed. An LVE holder must notify customers as needed about the conditions in the LVE by label, written communication, or other method that adequately informs downstream companies about the restrictions and controls.

Obligations continue to apply to an LVE holder once EPA approval is received. The regulation requires companies to notify EPA if new "test data or other information indicating that the new chemical substance may not qualify under terms of this section. . . within 15 working days" of obtaining that information. Records of compliance with the LVE must be maintained for 5 years.

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