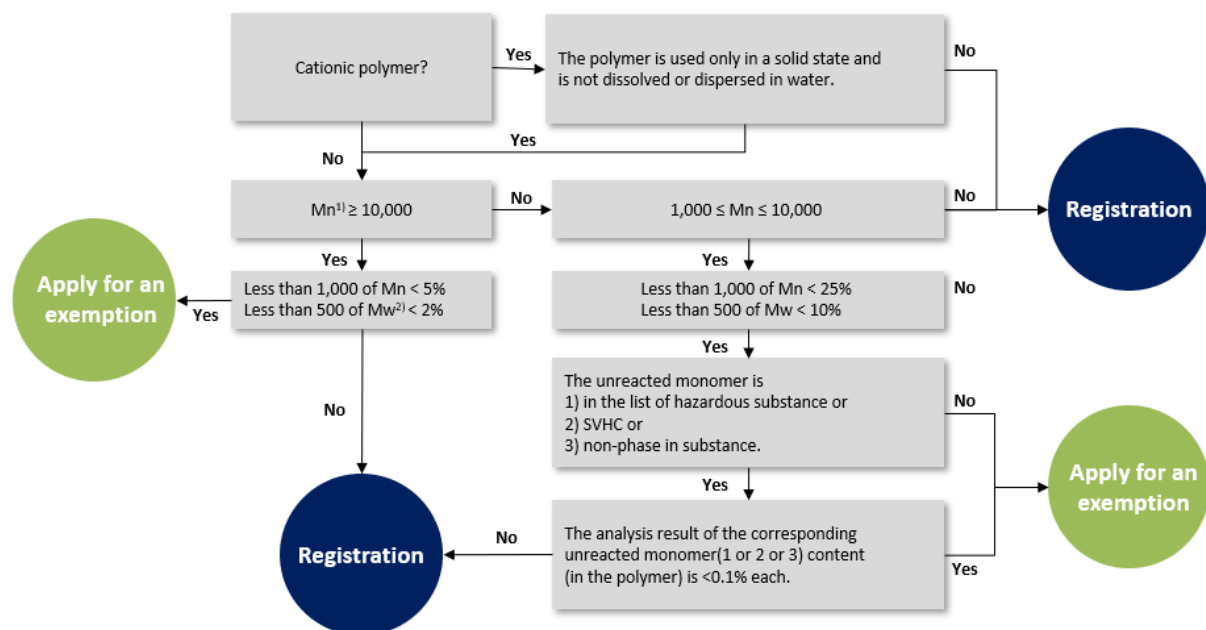


## Polymer registrations under K REACH

Polymers manufactured or imported into South Korea at more than 1 t/y are subject to registration under K REACH, unless the polymer meets the PLC (Polymer of Low Concern) criteria. There are basically two approaches to be considered when a substance meets the definition of a polymer under K REACH, one is a full registration and the other is applying for an exemption. If you are importing polymers to the Korean market, you should identify which of the two approaches applies to your case. Polymers known as Polymer of Low Concern need to fulfill the conditions below (see chart) and are subject to exemption from registration. You can apply for an exemption in the K REACH IT system during the grace period, regardless of the quantity of the polymer, as long as you have pre-registered your polymer. If you are not a pre-registration holder, you can apply for exemption prior to the manufacture or import of the polymer.



- 1) Mn: Number Average Molecular Weight  
2) Mw: Weight Average Molecular Weight

To apply for an exemption, you must submit the required evidence to prove that the polymer is exempted. The data requirements are as follows;

- Substance name, CAS/KE-No., and content ratio(%) of the monomer compositions (Note: monomers less than 2(w/w)% are excluded.)
- Analysis data showing Number Average Molecular Weight (Mn) and Molecular weight distribution
- Analysis GPC data on weight less than 1,000 of Mn and less than 500 of Mw
- Content analysis data on the unreacted monomer

### Definition of polymers and monomers under K REACH

The definitions of a polymer and monomer under K REACH are the same as under EU REACH.

With a monomer being a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. In other words, it is a substance which, via the polymerization reaction, is converted into a repeating unit of the polymer sequence.

In order to determine whether the substance is a polymer, it needs to satisfy all the following requirements; ([Link](#))

Polymer definition under K-REACH	Requirement information
A. It shall be composed of molecules in which at least one kind of monomer unit is continuously repeated.	Monomer information, chemical structure
B. It shall represent the characteristic distribution of molecular weights in accordance with repetitive numbers of monomer units in each molecule.	Analysis data (ex, GPC)
C. Its molecules that at least three monomer units form a covalent bond with at least one monomer unit or other reactants shall be at least 50 percent.	Analysis data (ex, GPC) (Mn, Molecular weight distribution)
D. Its molecules of the same molecular weight shall be not more than 50 percent of the weight ratio.	Analysis data (ex, GPC) (Molecular weight distribution)

Under K REACH, the definitions of existing chemical substances and new chemical substances are also applied to polymers. Polymers which were distributed in Korea for commercial purposes before February 2, 1991, are considered existing polymers. Otherwise, they are considered new polymers.

This means that the same grace period of existing chemical substances by tonnage band are applied to polymers as well.

### How to form a CICO for polymers?

CICOs (Chemical substance Information Communicative Organization, K-SIEF) are created for each individual chemical substance and therefore also for polymers. With each polymer available in a variety of different grades, the question on how to group polymers is a key point in the registration of polymers under K REACH. According to the latest guidance on polymer registration released by the Ministry of Environment (MoE) in September 2020, sameness of a polymer basically depends on the information of monomer(s) used in the polymerization. This means that even if the Number Average Molecular Weight (Mn) and monomer content of polymers are not the same, a joint submission is possible when polymers are considered to have the same monomers and reaction products. Nonetheless, the molecular structure and functional group should be considered for the hazard assessment of the polymers. There are some cases when monomers are the same; the CAS numbers are different due to differences in chemical structure. In this case, an extra CICO will be created, but a read-across approach can be applied to minimize the number of new tests required.

### Data requirements of a Joint submission for polymers

If data on physicochemical properties varies among the CICO members due to the variation in monomer content and Mn values, individual physicochemical property data need to be

provided by each single member company of the CICO. Nonetheless the physicochemical data can be provided jointly by grouping of the polymers based on Mn. For health and environmental properties the CICO members should choose a single data set for each endpoint representative for the polymer. The guideline contains methods on how to determine a representative data set for these end-points. With the exception of the before mentioned requirements, the same toxicological, ecotoxicological and risk assessment data as existing chemical substances need to be submitted for polymers.

Test material decisions will be a challenge for the registrants if a new study for registration is required. They can select several grades of the polymer to confirm the potential hazard in accordance with the molecular weight. In general, a polymer with the lowest Mn is considered the most harmful, but this is only applicable when the polymer does not have any other harmful elements, functional groups, or counter ions (metal ion). If the polymer has any of those, an equivalent mass of the harmful element and functional group need to be examined. The new guidance implies that the reactivity of a polymer is affected by the number of monomer units participating in the polymerization, therefore, the equivalent weight of the hazardous components need to be identified and registrants should select conservatively appropriate test material for their polymer. This will require active data sharing and discussions within the CICO.

### **How to prepare a SID report for polymers?**

The new polymer guidance contains detailed information on the measurement, method, and solvent etc. for substance identification. For example, the recommended analysis methods for molecular weight distribution are GPC, osmotic pressure method, light scattering method and intrinsic viscosity method. When the molecular weight of each molecule is low and it is difficult to separate the low molecular weight polymer with GPC, HPLC measurements are allowed as an alternative.

### **What about NLP (No Longer Polymers) with the same monomers as the polymer?**

The guidance specifies that if a) all uses and exposure scenarios of the polymer and NLP are identical, b) it is not a cationic polymer and, c) unreacted monomers being on the list of hazardous substances, or considered a SVHC, or a non-phase-in substance are present at less than 0.1% in the polymer, the polymer does not have to be registered separately from the NLP. The potential registrants should register the substance with a combined tonnage of both NLP and polymer. This is considered a very cost-effective strategy, as the NLP has already been registered under EU REACH. This means data sets for a full registration are already available. It will also help registrants avoid unnecessary animal testing. To benefit from this approach, registrants need to justify that the same hazard classification is applicable to both NLP and polymer. The minimum information required to predict the hazard properties of a polymer are toxicokinetic data as deduced from physicochemical properties and the molecular structure analysis. Toxicokinetic data are not mandatory requirements, but it may be helpful to make a robust justification through predicting the behavior of polymer molecules.

### **What can be challenges for polymer registrants**

The differences between K REACH and other global regulations on polymers will cause additional burden on many registrants. Identifying substances that fall under the polymer

definition and separate them into groups which are subject for exemption and for registration can be a challenge. Several parts of the polymer guidance from the Korean government are unclear on risk assessment and the guidance may not be sufficient to cover all the various use cases. Collecting use information on polymers will be a challenge due to the wide application of polymers. It will also not be easy for registrants who have already experienced monomer registrations under EU REACH, as they have never addressed polymer use information and will have signification data gaps.

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