



European
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CLEPA
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JAPAN AUTOMOBILE MANUFACTURERS ASSOCIATION, INC.



Position Paper

Exposure Scenarios for Mixtures /
Extended SDS for Mixtures



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BACKGROUND

The EU REACH Regulation requires that substance registrants complete a chemical safety assessment (CSA) and document this in a chemical safety report (CSR) for all substances manufactured or imported at 10 tonnes or more per year per registrant (Article 14 REACH). This CSA must be performed and documented in the CSR according to the 'General provisions for assessing substances and preparing chemical safety reports' (Annex I REACH) for substances on their own, substances in mixtures and substances in articles.

The legal text does not require exposure scenarios to be prepared for mixtures themselves. However, formulators for example have a legal obligation (Article 31.7 REACH) to forward to their customers information relevant to exposure to their mixtures, which they have obtained from the exposure scenarios (ES) attached to the SDSs for their ingredient substances. Such forwarded information includes conditions of safe use ('operational conditions' (OC) and 'risk management measures' (RMM) relating to substances supplied. Moreover, end-users of mixtures need to know how to handle those chemical products safely.

Suppliers of substances are required to provide the ES in an annex to the SDS, as a so-called extended SDS (Ext-SDS). ECHA Guidance on the compilation of safety data sheets (V3.1, Chapter 2.23) describes five options for suppliers to communicate contents of the substance ESs used in their mixtures:

1. Attachment of the actual exposure scenario(s) resulting from a CSA for a substance as such or exposure scenario resulting from CSA for a substance in a mixture in concentrations above the thresholds given in Article 14. In this case, at least a summary of the relevant key information from the attached exposure scenario must be included into the core sections of the SDS, with a cross-reference to the details in the exposure scenario;
2. **Integration of exposure scenario information resulting from consolidation of various exposure scenarios for substances used in a mixture into the core Sections 1-16 of the SDS;**
3. Attachment of exposure scenario resulting from the CSA for a special mixture;
4. (Potentially) attachment of exposure scenario resulting from a CSA for a mixture under Article 31(2) of REACH₁;
5. Append safe use information for the mixture (SUMI) derived from the exposure scenarios of the component substances.

For the automotive industry (AI) Option 2 above is preferred. In the case of a very complex mixture, for example with more than 5 ESs attached to the SDS, containing many hazardous ingredients for



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which the supplier received separate Ext-SDSs, it may be meaningful to initially prepare a consolidated summary of the separate substance ES contents in a special SUMI attachment, especially with regard to the environmental operational conditions for the lead substance.

For such a SUMI, the AI requests that a binding standard method, format and phrases should be developed by ECHA in consultation with industry associations. However, the AI recommends that the information obtained via a SUMI should then be integrated back into the main body of the SDS as in Option 2 above.

If a downstream user 'DU-CSR' according to annex XII has to be created (e.g. for any use outside the conditions described in an ES or for any use the supplier advises against), each single ES of the relevant substances has to be attached to the mixture SDS.

For the sake of clarity, it is desirable to use the REACH terminology for substances only for substances, and not for mixtures. For example: the term 'CSA for mixtures' should be replaced by terms such as 'consolidated risk assessment of mixtures' or 'consolidated advice for handling and use of mixtures' or 'consolidated OC and RMM'; 'exposure scenario for mixture' should be replaced by 'safe use mixture information (SUMI)'.

Note however, that the AI prefers to avoid putting emphasis on the DU-CSR (according to Article 37.4 & Annex XII REACH), since the preferable options are scaling and upstream communication.

Moreover, considering that CLP for mixtures is already completely implemented, and that CLP is very specific in describing the hazards of a mixture, it may therefore be determined that there is no real need at this time to develop a new method for determination of 'risk assessment for mixtures', because based on the CLP hazards for mixtures it is relatively easy to identify the appropriate RMM.

The automotive industry associations ACEA, CLEPA, JAMA, JAPIA and KAMA therefore support the concept for mixtures of integration of substance ES information into the core Sections 1-16 of the mixture SDS whenever possible, and request that this approach is followed throughout the supply chain.

Furthermore, the automotive industry associations above wish to draw attention to the obligation of suppliers to check ES of their mixture ingredients in order to provide advice on safe use of chemical product to their end-users. For this reason, suppliers of chemical products must confirm that the identified uses of themselves and of their customers are covered by the incoming ES of the single ingredients.

In this context, the AI also supports¹ the use of common formats and standard phrases (www.euphrac.eu) as well as XML-data exchange (www.esdscom.eu).

¹ https://www.acea.be/uploads/publications/02052013_Positionpaper_EDAS_SDSCOMXML_final.pdf



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ABOUT ACEA, CLEPA, JAMA, JAPIA AND KAMA

ACEA, the European Automobile Manufacturers Association, represents the 15 Europe-based car, van, truck and bus manufacturers: BMW Group, DAF Trucks, Daimler, Fiat Chrysler Automobiles, Ford of Europe, Honda Motor Europe, Hyundai Motor Europe, Iveco, Jaguar Land Rover, PSA Group, Renault Group, Toyota Motor Europe, Volkswagen Group, Volvo Cars, and Volvo Group.

- 13.3 million people – or 6.1% of the EU employed population – work in the sector.
- The 3.4 million jobs in automotive manufacturing represent over 11% of total EU manufacturing employment.
- Motor vehicles account for some €413 billion in tax contributions in the EU15.
- The sector is also a key driver of knowledge and innovation, representing Europe's largest private contributor to R&D, with €54 billion invested annually.
- The automobile industry generates a trade surplus of €90.3 billion for the EU.
- More information can be found on www.acea.be or [@ACEA_eu](https://twitter.com/ACEA_eu).

CLEPA brings together well over 100 of the world's most prominent suppliers for car parts, systems and modules and more than 20 national trade associations and European sector associations. CLEPA is the voice of European automotive suppliers, representing over 3.000 companies which employ 5.000.000 employees, invest over €20 billion yearly in R&I and provide solutions for safe, smart and sustainable mobility. www.clepa.eu/

JAMA, the Japan Automobile Manufacturers Association, established in 1967 is a non-profit industry association which comprises Japan's fourteen manufacturers of passenger cars, trucks, buses and motorcycles. Its organization today is the result of the merger of the Japan Motor Industrial Federation (JMIF) and the Japan Automobile Industry Employers' Association (JAIEA) with JAMA in May 2002. Directly or indirectly, roughly 9% of Japan's working population is involved in auto industry-related work. Auto production furthermore accounts for 16% of the total value of Japan's manufacturing shipments and for 37% of the value of the machinery industries' combined shipments. The automotive industry is thus one of the Japanese economy's core industrial sectors. The globalization of auto manufacturing also contributes significantly to local and national economies around the world. www.jama-english.jp/

JAPIA, Japan Auto Parts Industries Association was established in August 1969 on the foundations of a predecessor organization created in 1938. Its chief aims are to promote the sound development of the auto parts manufacturing industry and contribute to social and economic welfare.



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Today, with their annual turnover in auto parts exceeding 13 trillion yen, JAPIA members are helping to support the automobile industry on a global basis. <http://www.japia.or.jp>

KAMA, Automobile Manufacturers Association is a non-profit organization representing the interests of automakers in Korea. KAMA is dedicated to the sound growth of the automobile industry and the development of the national economy. www.kama.or.kr