

Compliance Analysis of M1 Vehicle Based on REACH Chemicals Regulation

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Abstract: Chemicals are essential for the well-being, high living standards and comfort of modern society. They are used in many fields, including health, energy, mobility and housing. However, most chemicals have hazardous properties which can harm the environment and human health. While the automobile industry, is an economic powerhouse for all over the world, it is important to keep the vehicle products REACH compliance. In this paper, it states the basic requirements of REACH regulation, the compliance strategy of automobile industry and the M1 vehicle products relevant analysis. At last, it gives the vehicle manufacturer proposal to evaluate vehicle products REACH compliance.

1. Introduction

Official Journal of the European Union issues the (EC) No 1907/2006 regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), December 18, 2006[1]. The European REACH Regulation came into force on 1 June 2007 and affects all industries. It requires immediate and ongoing action from the manufacturers and their suppliers. According to REACH, Substances of Very High Concern (SVHCs) should have been authorized or notified and substances which have unacceptable risk on human health or the environment may be restricted. Compliance with the REACH Regulation is mandatory for companies doing business in the EEA (and for businesses with customers or subsidiaries doing business in the EEA)[2].

Automobile products need to meet the (EU) 2018/858 regulations and obtain the (Whole Vehicle Type Approval) WVTA certificate when exported to the European market. As a Mandatory market supervision regulation, on one hand REACH regulation is difficult to be effectively identified, on the other hand it is easy to be ignored by automobile manufacturers. Therefore, if the manufacturers do not correctly and effectively identify the requirements of REACH regulations and actively respond to them, there will be high risk of non-compliance of automobile products, and the products circulating in the EU market will be forbidden to sell or even recalled, and the manufacturers will also receive severe penalties. The technical barriers formed by the mandatory implementation of REACH regulations obviously raise the threshold of coping with environmental regulations on materials and pose a greater challenge to vehicle manufacturers entering the EU market[1-2]. For example, the decision of the European Court of Justice (ECJ) on 10 September 2015 on the determination of SVHC content under REACH, which ruled that SVHC content should be calculated on the basis of components rather than the whole product, will have a huge impact on

companies.

2. General REACH obligation to vehicles

After REACH regulation come into force, it has a great impact on automotive industry. REACH imposes different obligations for each role: as a downstream user of substances and mixtures, a producer of articles (e.g. vehicle, engine, bumper manufactured in the EEA). Each actor in the supply chain play important role on it. And it should appoint a REACH representative and develop a strategic action plan to ensure compliance and minimise the business risks posed by REACH.

2.1. Scope and applications

Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. [1] From the definition, we can easily see that vehicle products, as the complex article, no direct obligation on the substances.

Preparation: means a mixture or solution composed of two or more substances; [1], So much Preparation is used on the vehicle products, for example, Cleaning fluids for automotive windshield, engine oil, antifreezing solution, refrigerating fluid and so on.

Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical Composition. [1] As we all know the vehicle has so many components ,such as steering wheel, seat, door, tire. It also give us an important signal which we should make sure all the components used on vehicles meet the requirements of REACH regulation.

2.2. General REACH obligation

Registration: Manufacturers or importers of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration for every substance to the European Chemicals Agency (ECHA), The registration involves the physical and chemical properties and toxicity of the submitted substance itself, and the registration needs the corresponding registration fee. Without registration, production and import will not be allowed. REACH has always followed the principle of no evidence and no market on this point. All registered substance information is available on the ECHA official website.

Authorization: In accordance with the requirements of Article 57 of REACH regulation, CMR substances with classes 1A and 1B specified in Regulation 67/548/EEC (CMR: carcinogenic, mutagenic, reproduction), PBT (persistent, bioaccumulations and toxic) vPvB (very persistent and very bioaccumulations), And substances with the same or similar toxicity as the above substances are included in the candidate list, called SVHC substances of high concern. The substances in the candidate list are screened and included in the authorization list in Annex XIV. Once included in the authorization list, the substance must be authorised by the authorised authority of the EU before it can be manufactured. It also sets a "sunset date" for these substances, before which the authorized substance can be produced. If the production is to continue after the sunset date, the application must be made 18 months before the sunset date, otherwise the production of the authorized substance after the sunset date will be a violation of the operation [3-4].

Information communication: If the substance in the candidate list contains less than 0.1% (mass percent), all suppliers shall provide sufficient information to consumers within 45 days of receipt of the request free of charge to make the item safe for use. A notification of SVHC substance to the

ECHA authority is required if the substance content in the candidate list is $> 0.1\%$ and the production or import volume is $> 1\text{t}$ per year. Article may be exempted from notification when, under normal conditions of use, exposure to humans or the environment can be ruled out, provided that the manufacturer or importer of the article provides appropriate information to the recipient of the article. As the candidate list is dynamically changing, it is updated about every six months, and the new added substances should be reviewed timely.

Restriction: If the substance by itself, or in mixtures, articles, and if the use of the substance poses an unacceptable risk to human health or the protection of the environment, it needs to be restricted within the territory of the EU. The list of restricted substances is contained in Annex XVII of the REACH Regulation and is updated irregularly. Substances in Annex XVII may increase or delete. Added substances is due to after the sunset date and it is still hazardous, then it will be added. While deleted substances are often due to its toxicity sub-classified required by other laws and regulations, bound to other laws and regulations to restrict the use of, for example: short chain chlorinated paraffin (CAS: 85535-84-8 EC 287-476-5) was removed from Annex XVII because of its persistent pollution and because it was added to the Persistent Organic Pollutants (POPs) regulation management. Since there are different types of restriction conditions for the substances in Annex XVII, the automotive industry should consider applicability.

3. Compliance strategy for vehicle

In view of the complex requirements of REACH, the vehicle products should be reviewed the target of their obligations to be fulfilled. Two aspects need to be considered for the vehicle product: oil auxiliary materials and components. See Figure 1 for an overview of the specific response process.

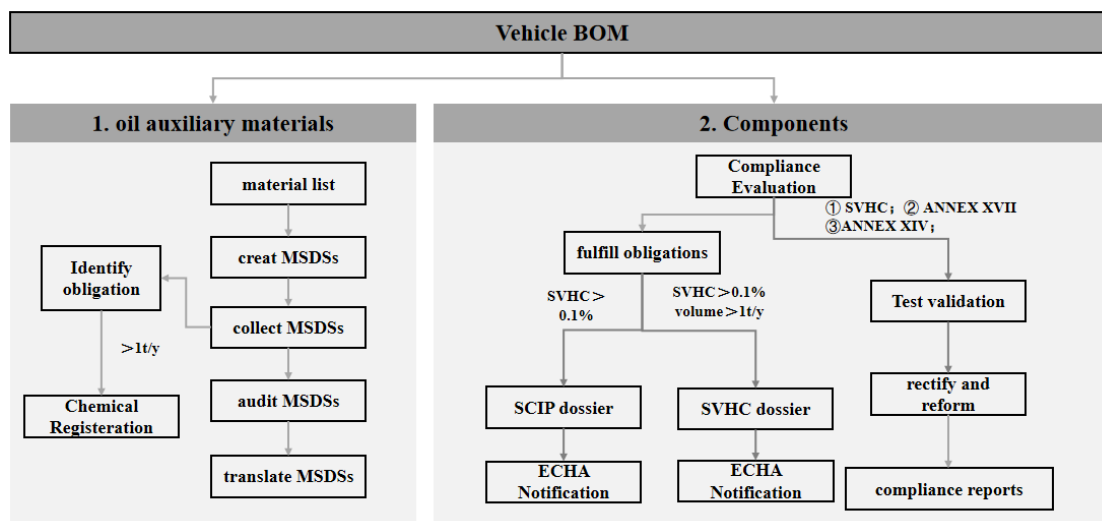


Figure 1. Process of vehicle to make REACH compliance evaluation

3.1 Oil and auxiliary materials

Regarding to oil and auxiliary materials, on one hand it involves the judgment of the registration obligation of substances, on the other hand it mainly involves the production of material safety data sheets (MSDS) and the versions in the official languages of the member States[5].

At first, it needs to be confirmed about the registration obligation, see the details in Figure 2.

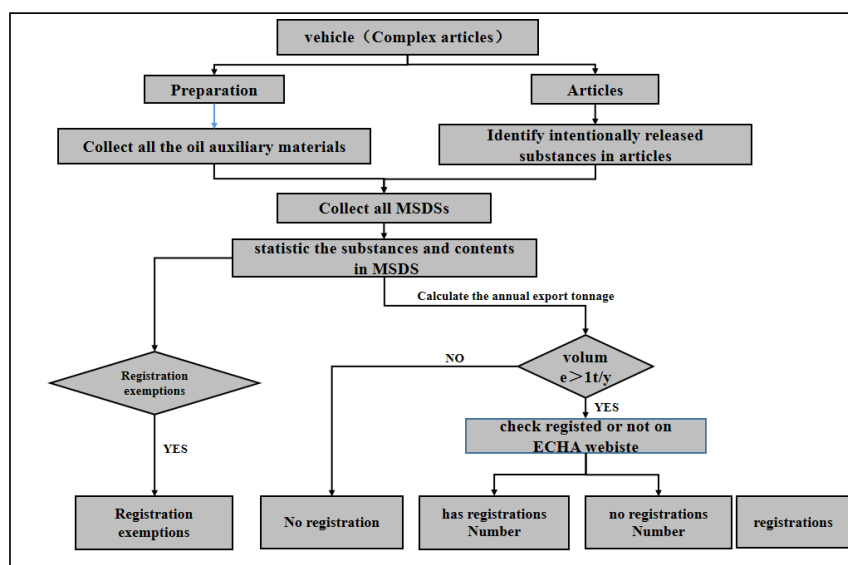


Figure 2. Process of oil and auxiliary materials obligation confirmation

According to Article 6&7 of REACH regulation, three categories of substance need to be registered: the substance itself, the substance in the mixture, and intended to be released in articles. But the registration obligation applies to the individual substances themselves, whether they exist alone, in mixtures or in articles. In other words, only substances must be registered under REACH, not for mixtures or articles. For automotive products, there is no application of the substance itself, so the registration of the substance itself is not suitable for automobiles. Automotive products mainly involve the registration of substances in mixtures and substances intended to be released in articles.

For the mixture, automotive products are mainly involved in the mixture types: paint, sealant, brake fluid, glass water, transmission oil, hydraulic oil and so on. By collecting MSDS reports of such mixtures, the information and content of substances in the above mixtures can be obtained.

For Intended to be released in articles the automobile industry may be involved in the assembly of the vehicle after the intended release of substances under normal conditions of use: (1) fragrance system; (2) fire control system (excluding portable fire extinguishers); (3) windshield washer system, (4) ignition device to release compressed gas. For example: airbags. Please note that although ignition devices using compressed gases are considered to be items that are intended to be released, the basic composition of hazardous and risky substances (hydrogen, oxygen, inert gases, nitrogen) is known and exempted from registration under ANNEX V(9) of the REACH Regulation. Other substances or preparations not listed may require registration.

Mixtures such as, but not limited to brake fluid, transmission fluid, battery acid, steering fluid, greases, screenwash and lubricants, that are in or on automotive complex objects are integral to the function of those complex objects, and therefore each mixture is considered to be an integral part of the complex object. They would therefore not require pre-registration and registration if contained in or on imported complex objects. These same substances in mixtures can however, require pre-registration and registration if imported on their own. [2]

The substance information and concentration information in the MSDS report can be used to calculate the volume for per vehicle, and determine whether the annual export volume/manufacturing volume exceeds the threshold of 1t/y, so as to determine the registration obligation.

3.2 Components

Because of the obligation of the REACH regulation is huge, so many substances needs to be controlled, vehicle manufacturers can take different strategies to achieve the final product compliance target, including: the whole supply chain of self-declaration, test verification, or the whole supply chain data information collection evaluation.

Self-declaration is a kind of guarantee through the car manufacturer to downstream suppliers. The supplier delivers the compliance information to the automobile manufacturer by providing the REACH compliance statement of the product. In case of non-compliance of the actual product, the supplier shall bear the corresponding responsibility. This method is simple and quick to operate, both the automobile manufacturer and downstream suppliers have saved a lot of economic costs and time costs. However, in this way, it is easy for the enterprises to pay little attention to the consistency check and reduce the attention to the response, which will bring great risks to the compliance of automobile manufacturers' finished vehicle products.

Because of Self-declaration risk vehicle testing can be carried out to reduce the product compliance risk of vehicle manufacturers. However, on the one hand, due to the complexity of testing various substances in REACH, the cost of vehicle testing is extremely high. On the other hand, for parts that do not contain substances in REACH, a lot of unnecessary testing activities are caused. Both in terms of time and cost, the strategy of tesing has some shortages.

Based on the advantages and disadvantages of the above two methods, through the whole supply chain material data collection of the vehicle (required by the EU RRR directive), the material data level of the vehicle can be used to investigate the substances in REACH regulations by information means. The high-risk substances, high-risk materials and high-risk components are sorted out, and then targeted testing are carried out. At the same time, the risk levels of the related substances of the vehicle are divided, which is convenient for enterprises to build their own high-risk database, so as to effectively cope with the EU REACH regulations.

4. Compliance analysis of vehicle

Based on the vehicle compliance strategy in chapter 3, a comprehensive evaluation of EU REACH compliance was conducted for two M1 vehicles.

4.1 Collecting material data on full supply chain

Since vehicle is a complex article, which is made up of thousands of parts, each part may involve the use of materials: steel, plastic, rubber, fabric, leather, oil, paint and so on. Each material involves a variety of substances. Generally, there are more than 1000 parts of the whole vehicle assembly level, more than 20 kinds of materials involved, and tens of thousands of material points related to REACH. Therefore, firstly, the whole supply chain data was collected through the vehicle BOM (Bill of Material) list, and the substance contents of the vehicle were sorted out through regular matching with SVHC, ANNEX XIV and ANNEX XVII of the REACH regulations.

MSDS reports of the chemicals in the vehicle should be collected based on the oil and auxiliary materials list of the vehicle, and the material information in the MSDS can be sorted out. In addition, in combination with the annual export volume of the EU, the substances whose annual export volume which are more than 1t/ year can be calculated, then the registration obligation will be clear.

Through there are about more than 100 kinds of substances in MSDSs for the whole vehicle, regarding to intended to be released in article registration obligations, manufacturer obtains a registration number sent by suppliers to confirm the registration obligations, because the remaining mixture is as part of the vehicle articles, and no exposure risk when the vehicle products cannot do

the registration , However, if the relevant suppliers put the mixture containing the relevant substance on the EU market separately, they still need to fulfill the registration obligation.

Collect MSDS and check their compliance based on the Oil auxiliary material list of automobile manufacturers. Please refer to ANNEX Q in REACH Automotive Industry Guide for detailed inspection procedures. See Figure 2 for details. SDS compliance audit process

The MSDS report after compliance review can be translated according to the official language of the target member state.

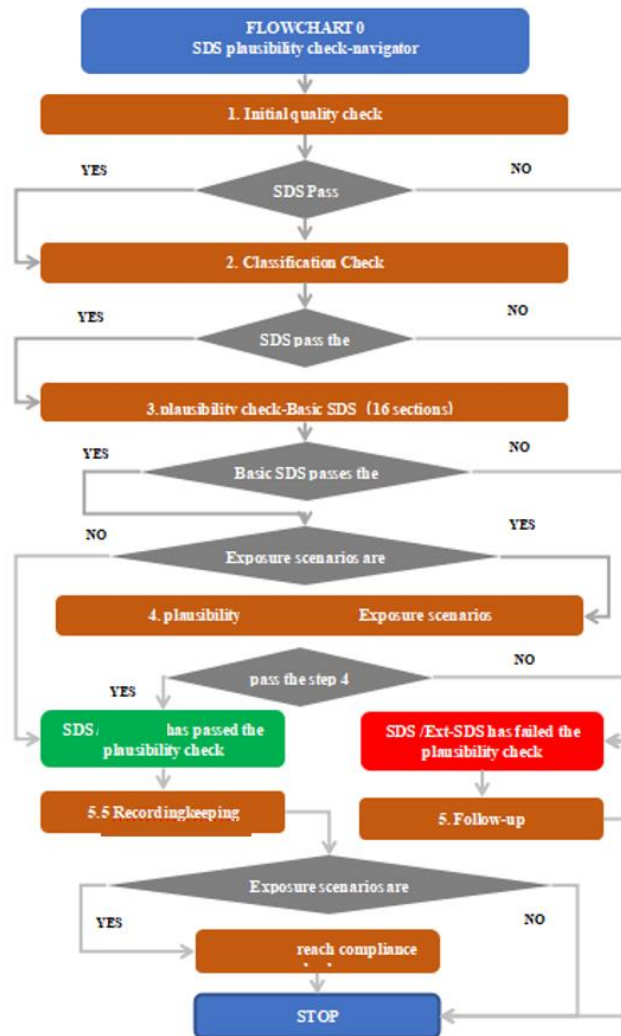


Fig. 3. SDS compliance check navigator [2]

According to the latest SVHC list published up to Jan, 2023, ANNEX XIV, ANNEX XVII and other material lists, the compliance evaluation of MDS (from IMDS or CAMDS) in the vehicle material data sheet was conducted according to the substance contents, and it will be comprehensively determined based on the substance contents in the SVHC, then to confirm the correlation between the substances in ANNEX XVII and automotive industry. The risk evaluation rules see Table 1.

Table 1: REACH risk evaluation rules

Substances category	High risk substances	High risk materials	High risk components
SVHC	1. Homogeneous materials with SVHC content > 0.1% are not exempt from SCIP* notification 2. Substances potentially added to ANNEX XIV	Contains a high-risk hazardous substance, and contains the material node number of the substance ≥ 20	Parts containing high-risk substances
ANNEX XIV	Substances in ANNEX XIV		
ANNEX XVII	Substances in ANNEX XIV		

* SCIP is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD). Companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market have to submit information on these articles to ECHA, as from 5 January 2021.

Based on the Material Data Sheet and the substance list of REACH, we can find the SVHC substances in vehicles. See some typical substances and applications in Table 2

Table 2: Typical applications of SVHC substances in components

Substances Name	CAS No.	Materials	Applications	Components
diboron trioxide	1303-86-2	Glass, PCB ceramic materials, etc	Manufacture BORON glass, optical glass, Pyrex glass and glass fiber, ceramics, etc., also used as paint flame retardant and desiccant	Sensor, instrument assembly, antenna, engine assembly, etc
Lead oxide	1317-36-8	Glass, PCB ceramic materials, etc	Used in the manufacture of polyvinyl chloride plastic stabilizer, high refractive index optical glass, ceramic glaze, precision machine tool plane abrasive,	Sensor, antenna, engine assembly, etc
Diisobutyl phthalate	-	PVC, NBR	elasticizer	Rear view mirror assembly, trim assembly, etc
Azocolourants and Azodyes	-	Neoprene, polyethylene, EPDM	blowing agent	Trim assembly, decorative plate assembly, shock absorption glue, etc
boric acid	10043-35-3	zinc coating	stabilizer, buffer	Door trim plate assembly, door glass lifter assembly, screws, nuts, bolts, etc

As for ANNEX XVII, based on the testing data and REACH industry guidelines, the substances in ANNEX XVII will be checked for their correlation with automobiles, and the substances closely related to automobiles and with high risk will be checked, as shown in Table 3. On this basis, the enterprise should combine the material selection of its own supply chain, conduct material investigation according to the material basis list in ANNEX XVII, and then conduct impact evaluation according to the following high-risk list.

Table 3: REACH Annex XVII Impact Evaluation for automotive industry

Entry No.	Restricted substances	CAS No.	Use in process chemicals (PC) or Articles (Art)
entry 1	Polychlorinated terphenyls (PCTs)	-	PC/Art
entry 4	Tris (2,3 dibromopropyl) phosphate	126-72-7	Art
entry 5	Benzene	71-43-2	PC
entry 6	Asbestos fibres	-	PC/Art
entry 7	Tris(aziridinyl)phosphin oxide	545-55-1	Art
entry 8	PBB	59536-65-1	Art
entry 20	Organostannic compounds	-	PC/Art
entry 21	DBB	75113-37-0	PC
entry 23	cadmium	7440-43-9	PC/Art
entry 24	Monomethyl - tetrachlorodiphenyl methane Trade name: Ugilec 141	76253-60-6	PC/Art
entry 25	Monomethyl-dichloro-diphenyl methane Trade name: Ugilec 121, Ugilec 21	81161-70-8	PC/Art
entry 27	Nickel and its compounds	7440-02-0	Art
entry 43	Azocolourants and Azodyes	-	PC/Art
entry 45	Diphenylether, octabromo derivative C ₁₂ H ₂ Br ₈ O	-	PC/Art
entry 47	Chromium VI compounds	-	Art
entry 48	Toluene	108-88-3	PC
entry 49	Trichlorobenzene	120-82-1	Art
entry 50	PAHs	-	Art
entry 51	Diisobutyl phthalate	-	Art
entry 54	2-(2-methoxyethoxy) ethanol (DEGME)	111-77-3	PC
entry 55	2-(2-butoxyethoxy) ethanol (DEGBE)	112-34-5	PC
entry 57	Cyclohexane	110-82-7	PC
entry 59	Dichloromethane	75-09-2	PC
entry 60	Acrylamide	79-06-1	PC/Art
entry 61	DMF	624-49-7	Art
entry 69	Methanol	67-56-1	PC
entry 71	1-methyl-2-pyrrolidone	872-50-4	PC/Art
entry 76	N, N-dimethylformamide	68-12-2	PC

In the table it was only considered process chemicals (PC) and articles (Art) used in the vehicle and in automotive related products. Furthermore only automotive article manufacturer and their typical production processes are taken into account.

Art: Relevance for articles incl. spare parts

PC: Relevance for substances used in the production process (process chemicals) Relevance for automotive aftersales chemicals products.

Art/PC: Relevance for articles (incl. spare parts) and process chemicals (incl. aftersales chemicals products)

According to the Table 1&2&3, the final high risk list will be created. And then combined with testing verification, the fixed high risk can be created, then the manufacturer build their own high risk database.

5. Conclusion

(1) Vehicle products exported to EU market must make compliance strategy for REACH regulations, timely track the changes in the substance list of regulations, and conduct compliance evaluation work.

(2) Collecting vehicle material data through information means (CAMDS or IMDS) as the basis for REACH substance risk assessment is an effective method for data compliance analysis.

(3) Automotive electronic wiring harnesses, interior decoration, sealant, paint and other parts, as

well as phthalic plasticizers, Azocolourants and Azodyes, asbestos, Cd and Pb and other substances need to be paid attention to in SVHC and ANNEX XVII.

(4) Manufacturer should build vehicle database internally, dynamically manage the information of harmful substances of enterprises, reduce costs and ensure product compliance. Due to frequent revision of REACH regulations, the substance updates of SVHC and ANNEX XVII are more frequent, and complete vehicle products need to be based on the compliance of the whole supply chain. Therefore, manufacturer can build a database of hazardous substances, dynamically manage the high-risk list of products, and update current events, which can help enterprises effectively cope with the compliance of REACH regulations.

References

- [1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
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