REQUEST FOR ADDITONAL INFORMATION

Legal name of applicant(s):	Monroe Czechia s.r.o.
Submitted by:	Monroe Czechia s.r.o.
Date:	13 August 2021
Substance:	Dichromium Tris(chromate)
Use title:	Use of dichromium tris(chromate) in a post-treatment step of the autodeposition coating process of shock absorbers for automotive vehicles.
Use number:	Use 1
Communication Number:	AFA-C-2114563152-56-01/F
Submission Number:	TQ831466-08

	ECHA Request	Applicant Response
CSR questions		
1	Please clarify how the 95% effectiveness of the RPE used during the tasks with potential to exposure to Cr(VI) (full face or half face mask with ABEK1 + P3R filters) was estimated.	The full or half face masks used in the plant are suitable for the particular hazards, thus providing a high level of protection from exposure to Cr(VI). As per the documentation of the masks, half masks can protect at up to 10 times the maximum permissible concentration and full masks up to 200 times. Considering the very high level of protection offered by the RPE used at the plant, a 95% effectiveness was considered an appropriate value.
2	Related to the static measurements performed: a. Please provide the sampling duration for the static measurements performed 20 cm above the reactive rinse bath, provided in Annex A of the CSR. b. Please also specify the limit of quantification of the analytical method used to perform the Cr(VI) concentration monitoring (Method no. ID-215, v.2).	a. Measurement duration: whole shift (min. 6 hours) b. 0.2 µg/m^3 according to the Method protocol
3	In the CSR you presented the static measured data as a worst-case scenario for the worker's exposure assessment and used them for the risk characterisation. Please explain (using comparing values if possible) why modelled data were not considered for the risk characterisation in case of WCSs 3, 4, 6 and 8.	In the CSR (Section 9.1.4, page 20), modelling results are used only when monitoring data are not available. Monitoring data are based on actual conditions at the plant and can better describe actual exposure than estimated results. In some cases, such as for WCS 4, the static monitoring data is also considered a conservative result, because the operator is working further away from the monitoring station, which would result in even lower exposure. For the mentioned WCSs (3, 4, 6 and 8), there is monitoring data available, so for the reason explained above, it was selected for the risk assessment.
Exposure of human via environment		
4	In the CSR (section 9.1.1.2 release to air) and as confirmed by the answers you already provided, the emissions to air that occur in the rinse bath are indicated as fugitive. There are however quantifiable emissions used to calculate airborne concentrations and human	The emissions are described as "fugitive" in the sense that there is no dedicated LEV or other exhaust system over the ACC line, as there is on the Hard Chrome Plating lines, and, due to the room temperature of the reactive rinse bath, there is not increased generation of vapours.

	exposure via the environment. It doesn't seem appropriate to define these emissions as fugitive. Please provide a detailed explanation of the ventilation system and how the volumes of air exchange in the rinse bath (1-3 air change/h) are guaranteed and managed. Also provide an explanation through which points the air is released into the environment (e.g. chimney/stack). Please explain if additional RMMs are implemented to limit the releases during the operation of the ACC line.	In the ACC area, there is general ventilation, which, as mentioned in the CSR, achieves approximately three air changes per hour. The inflow of air in the production building (and the ACC area) is achieved through distribution pipes along the length of the building. The air exchange achieved in the ACC area is verified by calculation of the incoming air from the general ventilation system in place. DRiV constantly (24h per day – 365 days a year) monitors the electric motors of the main air make-up units automatically, through the plant's central control panel. If they operate nominally, DRiV has calculated the volume of incoming air, which corresponds to approximately 3.3 air changes per hour (3 air changes per hour used in the calculations below). DRiV thus monitors the continuous operation of the ventilation and ensures its good condition with regular maintenance: ■ Twice a year change of filters and belt pulley inspection ■ Once a year external control of electric regulation system] ■ Once a year external control of gas burner The ACC exhaust system is independent of that on the HCP lines. There are four stacks on the ACC line, but Cr(VI) was only measured at the stack on the curing furnace / oven. Cr(VI) from the process is released through the furnace stack, as the draft generated at the furnace entrance draws air from over the reactive rinse tank. Based on the results from the monitoring campaigns, concentration of Cr(VI) in the ACC line is below the OELs set by the Czech authorities (as presented in section 9.2, p.24 of the CSR and in the response to RAC Q.2 in the first request for information), so there was no need for additional RMMs. It should be noted that, as mentioned in section 9.1.4.1 (page 20) of the CSR, exposure to Cr(VI) from the ACC line operation comes from both DCTC and chromium trioxide used in the reactive rinse bath. Even though chromium trioxide is out of scope of this AfA, it was decided to carry out the exposure and risk assessments for the total Cr(VI) from the process, irrespective of substance, as a worst-case approach.

5	Please provide a detailed description of the calculation of PECair at local and regional level and clarify which one is used for the assessment of the HvE exposure.	Local air concentrations were calculated using Chesar, with input parameters as shown in the table "Conditions of use" in page 29 of the CSR. The daily release rate, which is used as input, was calculated using the static monitoring measurements at the reactive rinse bath, as shown in Table 9.5 (page 30) of the CSR. The 90th percentile of the static monitoring results (0.371 µg/m^3) was multiplied by the volume of the ACC area (32m x 22m x 6.7m = 4,716.8 m^3) and the 3 air changes per hour to give an hourly release rate of approximately 5.25 mg/h. In an 8-hour day, this would result in a maximum release of 42 mg/day (4.2 x 10^{-5} kg/day). Using this value as an input, and assuming zero emissions to water and soil, Chesar gave an air concentration of 8 x 10^{-6} µg/m^3, as shown in Table 9.6 of the CSR. This value translates to an ELR of 2.32 x 10^{-7}, when using the inhalation ERR for the general population (2.9 x 10^{-2} per µg/m^3 for 70 years). The rationale for only considering inhalation for the HvE exposure assessment is described in Section 9.1.3 (page 18) of the CSR. Similarly, the regional PEC_{air} was calculated using the same input parameters in terms of daily and annual usage of DCTC and the calculated daily releases to air. Again, water and soil releases were assumed to be zero. The EUSES model within Chesar calculated a total release to air of approximately 0.01 kg/year, and a regional PEC_{air} of 4.58 x 10^{-12} µg/m^3, which translates to an ELR of 1.33 x 10^{-13}. Nevertheless, in the SEA it was decided to use the PEC_{oral} for the regional population exposure as a worst case, as EUSES had calculated a higher ELR from oral exposure (6.02 x 10^{-11}). For local population exposure, only inhalation ELR was considered, as described above. It should be noted that, as mentioned in section 9.1.4.1 (page 20) of the CSR, exposure to Cr(VI) from the ACC line operation comes from both DCTC and chromium trioxide used in the reactive rinse bath. Even though chromium trioxide is out of scope of this

		AfA, it was decided to carry out the exposure and risk assessments for the total Cr(VI) from the process, irrespective of substance, as a worst-case approach.
6	In the response to Q6 of the first round of questions, you provide information on the annual WWTP discharge rate and the Cr(VI) into water, which is around 0,06 Kg/year and apparently related to the sole hard chrome plating operations. Please provide further clarifications: a. How was this yearly discharge calculated? b. Provide an estimate of the quantity of Cr(VI) released annually attributable to the use applied for, despite this might represent a fraction of the overall WWTP discharge derived from all the operations occurring at the Hodkovice site.	a. The average content of Cr(VI) in wastewater after treatment at the WWTP was 3.07 µg/l. For a discharge of 20,000 m^3 per year, the total Cr(VI) releases are calculated as approximately 61.4 g/year (0.06 kg/year). b. In the first round of questions, DRiV estimated the amount of Cr(VI) from the ACC line treated in the WWTP as approximately [redacted] (0.5-15) g per year. Only the samples used for analysis are discharged to the WWTP, which are calculated at approximately 500 ml per year. The total annual discharge of the WWTP is 20,000 m^3 per year, so the wastewater from the ACC line treated there corresponds to 2.5 x 10^{-6}% of the total wastewater. Assuming the concentration of Cr(VI) in the other wastewater is the same as in the sample analysis waste, the released Cr(VI) corresponding to the ACC line will be approximately 2.5 x 10^{-6} of the 0.06 kg of Cr(VI) calculated as released from the WWTP, or approximately 1.5 x 10^{-9} kg/year (1.5 µg/year).
AoA/SEA/SP		
1	In order for SEAC to have a clear view of what types of shock absorbers would be coated on the second line in the NUS and which could not, please fill in the second column of the following table. Please note that in the following questions SEAC is using the term: “sub-group” (in line with page 33 of the SEA), but if the term “platform” or a different one is more appropriate please amend the terminology as needed.	As a general comment, the setup of the manufacturing plant in Hodkovice consists of two buildings, of similar shock absorber manufacturing capacity. Each of the buildings has its own coating line, one having the ACC and the other the spray line. Shock absorbers manufactured in one building are also coated in the same building, to reduce logistics complexity from having to transfer uncoated shock absorbers from one building to the other. Please, also keep in mind that this is a bridging application, with a short requested review period until September 2024. DRiV is committed to stop using DCTC in their ACC coating process by the end of the review period, as they work towards an alternative. So, the continued use is intended to carry on for a short period of time, with low releases and impacts. Therefore, any changes during this review period should be considered in terms of the very limited time before DRiV introduces a new technology.
	Questions on shock absorbers coated on the <u>ACC line:</u>	**Responses**

CBI 1

	i. *a.* How many sub-groups of shock absorbers are coated on the ACC line, and b. how much of the total production do they account for? c. provide a short description of the types of products which are in those sub-groups.	a…..Currently the ACC line is used for the coating of [redacted] (10-50) different platforms covering [redacted] customers b….The ACC line accounted for [redacted] % of total production, based on projections for 2021 and for [redacted] % based on projections for 2022. c. All products coated in the ACC line are shock absorbers, either monotube or double-tube. They differ only in their dimensions (e.g. rod or tube diameter, length of shock absorber), but the basic design is the same. The customers in question are [redacted]	CBI 1
	ii. Of the above shock absorbers which are coated on the ACC line: a. how many sub-groups are also validated on the second line (spraying) and b. how many are not (*i.e. how many sub-groups are only validated on ACC line*)? regarding points ii (a) and ii (b), how much of the total production do they represent? Please indicate the "%" in the brackets next to the number of sub-groups.	a. There are [redacted] sub-groups (corresponding to approximately [redacted] % of the total production in the plant in 2021 and [redacted] % in 2022) that are also validated on the second line. b. The remaining [redacted] sub-groups (corresponding to approximately [redacted] % of the total production in 2021 and 12.1% in 2022) are only validated for the ACC line. These subgroups belong to [redacted]. ** Based on the SEA page 33, SEAC understands that these are [redacted]. Please amend if needed.*	CBI 1

	Questions on shock absorbers to be moved to the second line in the NUS		
	iii. In connection to your response to ii (a) of this table, how many sub-groups of shock absorbers will be moved from the ACC line to the second line in the NUS? Indicate: a. the number of sub-groups that will be moved to the second line from ACC and b. provide a short description of the concerned products in those groups.	It must be stressed that the main factor determining the number of products that would move from ACC to the spray line is the capacity of the line and the limited time available for any validation work and transition to the alternatives. a. According to the 2022 planning, it will be possible to move coating of additional pieces accounting for approximately [redacted]% of total production in 2021 and [redacted]% in 2022, from the ACC line to the spray one. These will be only from the already validated sub-groups. The number and identity of the individual sub-groups cannot be defined, yet, as they will depend on the results of the negotiations with the respective customers, who must first agree with moving production of their part to a different line / technology. The share of products that will move to the spray line may be lower in the end, as a result of many customers refusing to have their parts produced in a different way. Customers do not support the approach of having to handle products from different technologies or lines, even if they are validated in both, as they may still have differences in quality, which could affect production downstream. b. As discussed in (a), the sub-groups that will be coated in the second (spray) line cannot be defined, yet, as their production will depend on whether the respective customers will agree with the product being coated at the spray painting line.	CBI 1
	iv. How many sub-groups of shock absorbers will not be moved from the ACC line to the second line in the NUS (and so would be lost)? Please provide total number of sub-groups that would be lost by also indicating separately the number of sub-groups that: a. cannot be validated on the second line (because the line is not able to meet high-end	As mentioned in the response to question 1(iii)(b) above, the total number of sub-groups that would be lost is not possible to specify at this stage, as it depends on negotiation with customers. There are some points to consider, as described below: a. As mentioned in the response above, there are [redacted] platforms / sub-groups not validated in the spray coating line. DRiV is not certain that they will be able to obtain	CBI 1

	specifications, in line with your response to the second round of questions) and b. cannot be coated on the second line because of its capacity constraints (even though the products are validated)? If possible, list in an annex all the sub-groups that would be lost in the NUS.	acceptable results in the various corrosion protection tests required for their validation. The corrosion protection tests must be carried out at an external laboratory and each carries a cost of approximately [redacted] (€1,000-10,000). A typical test has a lead time of 10-12 weeks, so DRiV estimates that the validation campaign for all [redacted] sub-groups could take approximately 12-18 months. If a test is not successful at the first attempt, DRiV will need to modify their process, produce the part and test it again. In addition, it should be noted again that the main factor determining the number and volumes of shock absorbers that could be produced is the capacity of the second (spray) line. The capacity shortage due to the capacity limitations would mean that only a part of the already validated sub-groups could potentially be spray coated. As such, pursuing the validation of the [redacted] non-validated sub-groups would provide no benefit, as there is not enough capacity to spray coat them. Considering that this is a bridging application, until DRiV introduces a new coating technology, with a short requested review period, the time, cost and effort involved in the validation, with uncertain results, would only be relevant for a short period of time (less than two years). b. In the AoA / SEA, it is mentioned that approximately [redacted]% (<35%) of the manufactured shock absorbers would be lost due to capacity constraints in the NUS. DRiV has recently re-evaluated the data based on 2021 and 2022 production forecasts and now estimates that approximately [redacted]% of total production volume would be lost in 2021 and [redacted]% in 2022. These numbers may be subject to further change as the production schedule is adjusted quarterly. The specific products that will be lost cannot be defined, but it is expected that the value of [redacted]% for 2022 includes [redacted]% of the non-validated products and a minimum of approximately [redacted]% of validated products that will be lost due to insufficient capacity. For 2021, these values are [redacted]% and approximately [redacted]% respectively.	CBI 1 CBI 1

	v. With regard to response to question "iv" of this table, how much of the total production do they represent ("a" and "b" altogether)?	As mentioned in the response to question 1(iv)(b) above, it is estimated that approximately [redacted] % of total production would be lost due to capacity limitations on the second painting line (approximately [redacted] million pieces in 2022). ***SEAC understands that they account for [redacted] % (1-5 million pieces), based on the information provided in the SEA (page 38). Please amend if needed.*
2	With regard to question ii(b) and iv(a) in the above table, please clarify why certain products cannot be validated on the second line (spraying). In your response to the second round of questions (response 2(a)), it is stated that this technology is not able to meet "high end product specifications". Please explain what these high-end specifications mean in practice and whether additional or different specifications than the standards reported in Mercedes DBL 7381.12 need to be met?	To give an illustrative example, DRiV recently explored the feasibility of coating the shock absorbers for customer X at the ACC and spray coating line. The dipping process of the ACC line provides advantages on corrosion protection of weld areas compared to the spray line, so it is easier to meet the customer's specifications. The technical reasons for failure to validate some sub-groups in the spray painting line are related to meeting corrosion resistance specifications, as specified by the customers. In addition, as discussed in question 1(iv)(a) above, there are still the capacity restrictions, which means that even if those validations were successful, there would not be sufficient coating capacity in the spray line and the validation would provide no benefit. As was discussed in the SEA, DRiV would need to carry out validation of all sub-groups / platforms in the alternative coating line that will eventually replace ACC after September 2024. In addition, as this is a bridging application with a short requested review period, the time needed to achieve validation (12-18 months) means that any benefits gained would be minimal and for only a short period of time (less than two years).
3	In the SP, the time for each phase is confidential and no public ranges were provided. Please confirm whether you agree with the following public ranges to be used in the opinion: a. process validation (between 5-10 months)	The proposed public ranges are acceptable.

CBI 1

	b. quotation and negotiation (between 5-10 months) c. installation of the new coating line and fine tuning of the process and (between 10-20 months) d. validation and qualification of products (5-15 months).	
4	Please indicate whether the second spray coating line (in the other building) requires the use of SVHC and whether – in your view - its safety profile is comparable to the two shortlisted alternatives.	There are no listed SVHCs among the chemicals used in the second spray coating line. However, the process requires the use of VOCs, due to the solvents of the paints used. Compared to the second spray coating line, alternative 1 has a better chemical safety profile, as it does not use any VOCs. Furthermore, there is possibility of recycling the material of the paint to be used again, thus increasing the efficiency of the use to near [redacted]%, thus reducing the material requirements. Alternative 2 still needs to use some VOCs, but less than the spray coating line, thus having a better safety profile as well. In addition, its efficiency is near [redacted]%.
5.	Regarding the process description on page 14 of the socio-economic analysis, clarify whether the whole shock absorbers or only the previously painted parts are treated in the ACC reactive tank (ACC bath)?	Only the previously painted parts are treated in the ACC reactive rinse bath. This can be seen in Figure 9.11 (page 41) of the CSR. The painted (purple in the photo) cylinder is immersed in the bath, while the unpainted rod (silver/grey in the photo) remains outside.
6.	Considering that the current use is not authorised, please indicate whether any arrangement is in place with the national enforcement authority.	DRiV has made the national competent authority aware of the situation on 6th of April 2021. DRiV spoke to three officials: the [redacted] DRiV discussed their situation over the phone and all contacted officials of the swift communication and of the proactive approach taken by DRiV. They have not requested any formal communication by DRiV. DRiV intends to keep the CA up to date of any developments regarding their AfA.

CBI 1

CBI 2

7.	SEAC considers introducing a condition for the authorisation to limit the scope of the use of DCTC to those shock absorbers which could not be coated on your second line (spraying) in the NUS. a. Please indicate whether in case the authorisation is limited to these shock absorbers, the loss in output of [redacted]%(<35%) would be avoided. Please link the response to this question to the responses provided to question "iv" and "v" in the above table. b. Please describe any relevant impact (e.g. any relevant economic or technical implication) which might be associated with such a condition. Please, make sure that the impacts discussed are consistent with the assessment included in the socio-economic analysis and in the responses provided in the table above.	It should be noted again that this AfA is being made as a bridging application with a short requested review period until September 2024. DRiV is committed to stop operation of the ACC line by that date and to install a new line, based on Cr(VI)-free technology. As such, any benefits gained by, e.g. reduced use of DCTC in the ACC line, would be very low and for only a short period of time. a. If the authorisation condition was only limited to the [redacted]% (<35%) of the shock absorbers that it would not be possible to coat in the second line (as per the response to Question 1(v) above) then that loss may initially be avoided. The actual quantities that may still need to be coated in the ACC line would depend on the orders and the production schedule, which is updated quarterly. The remaining volume to be painted in the ACC line is a fraction of its total capacity, and running the ACC line at a lower capacity is not efficient, especially in a manufacturing plant that operates a lean production schedule, with minimal lead times and storage requirements. The ACC and the spray lines are each fed by the manufacturing lines housed in their respective buildings. As soon as the shock absorbers are assembled, they are sent for coating in the ACC line. The ACC line will thus have to be able to accept the shock absorbers as soon as they are ready, so it has to be operating at all times during production. This means that it will consume the same energy and other utilities and emit the same amount of Cr(VI) from the reactive rinse bath. As a result, the production cost per unit will increase compared to the applied-for use scenario. Furthermore, the start-up costs of the ACC line are high, as they include the cost to start and maintain the curing oven after the reactive rinse step. If the ACC line remained operational only for as long as was needed to coat the shock absorbers that cannot be coated in the spraying line due to capacity constraints, there would be significant additional costs, due to the need for storage capacity, which can only be sourced by external warehouses. DRiV estimates that the storage volume required for a week's production is approximately [redacted] (100-500) m^3 and could carry additional cost of €[redacted] (€100,000-500,000) per week. There is significant cost associated with the storage of this volume at an external warehouse, but it also presents an additional logistical challenge, as the shock absorbers will need to be	CBI 1 CBI 1

		transferred back and forth, thus reducing the overall efficiency of the plant and also increasing the unit cost. b. The practical implications of operating the ACC line at such a reduced capacity are discussed in part (a) of this response. In summary, operating the ACC line only for less than half its current output would significantly increase the unit cost of the shock absorbers produced there. This will be in addition to the higher cost per unit of the spray coating line (approximately €[redacted] (€0.01-0.1) per piece or ([redacted]%) 10-50% more expensive than the ACC line). The rearrangement of the production plan and the higher costs per unit could have unexpected reactions from customers. DRiV's customers may not want their part to be moved to the spray coating line, as they would have to handle parts produced in two different lines, which could impact their own manufacturing processes. Thus, there is the risk that they could eventually withdraw their orders with DRiV. This would lead to a significant loss of business for DRiV, and to loss of employment for their employees. This would also decrease the competitiveness of the products offered by DRiV and is expected to also affect future business earned by the company. Furthermore, running the spray line almost at capacity will reduce flexibility of the production schedule and would make it vulnerable to delays and difficult to accept additional orders, either from customers or from another DRiV manufacturing plant. If the spray coating line had to take shock absorbers manufactured at the building of the ACC line (monotube), it will limit the capacity of the double-tube manufacturing plant to expand its operations. This extends to the DRiV manufacturing plant in Hodkovice as a whole. Limiting the capacity of the ACC line will essentially limit the capacity of the whole plant to expand in the near- and mid-term. The maximum capacity of the plant will thus be reduced from approximately [redacted] million pieces now to between a half and two thirds of that. Finally, another cost element to consider is that related to the stock of chemicals used in the process, in particular the Bonderite formulations used in the ACC lines. As these

CBI 1

		are produced in batches sufficient for a 6-month production by DRiV's supplier, and as DRiV is the only customer for that formulation, if production schedule changes, these chemical agents would have to be disposed of. Such a cost has already been discussed in the SEA.

Annex A: Justification for confidentiality claims

Blanked out item reference	Justification for confidentiality
CBI 1	**Demonstration of Commercial Interest:** Volume of sales, revenue, profits, employment and other economic information are confidential information that are only to be used for the Applicant's planning and operations. Sharing them publicly may also breach anti-trust and competition laws in the EU. **Demonstration of Potential Harm:** If competitors got hold of this information, they could use it to determine the Applicant's market share or the weight of the particular products on their overall business. Competitors could use such sensitive information to gain a competitive advantage over the Applicant. Some of the redacted information could also be used to back-calculate sensitive information. **Limitation to Validity of Confidentiality:** This claim is valid indefinitely.
CBI 2	The roles of the people that DRiV contacted in the national competent authority to inform about the situation were redacted to protect the identity of those officials.