CHEMICAL SAFETY REPORT

Lead chromate (CAS 7758-97-6 / EC 231-846-0)

This CSR is part of the 3 documents (CSR/AoA/SEA) in support of the ***application for authorisation***
submitted by the Company ***ETIENNE LACROIX TOUS ARTIFICES SA***
for the use-1 titled:
"Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection"

9.3. Exposure scenario 3: Formulation of the pyrotechnical composition, filling the delay devices with it, and scraping the top of the powder column before closing each device

ES-3 is the key exposure scenario. Exposure assessment is based on monitoring/biomonitoring data. The two sub-stages, on one side the formulation of the composition, on the other side the use into delays, are closely associated and very similar. Notably, handling temperatures are the same, and the operations take place in the same rooms and are conducted by the same operators.

Firstly the pyrotechnic composition (mixture) is prepared. The mixture contents lead chromate, lead tetroxide, silicon, and silicon dioxide. Secondly, the operators fill the "composition" into the delay devices, with compression the powder.

After the stocking in glass bottles and the shooting tests, the level of the "composition" column is adjusted in the devices, and the devices are closed.

All these manipulations take place in two dedicated rooms with the help of tools. A semi-confinement of the working area, notably with polyethylene screens and aspirations very close to the point where the lead chromate composition is handled, reduces the exposures of the workers (Figure 2/ Figure 7 / Figure 8).

LACROIX clearly identified this scenario like the one with SVHC concern. The Company is aware that this stage requires strict management measures to comply with legislation and to protect as far as possible the workers.

The needed Authorisation is in that way very simple: it applies specifically to this ES-3 stage that takes place in one building (Figure 2) at one site and concerns maximum 12 workers (Table 11).

Table 11: Summary of the exposure scenario-3

Identifiers	Use descriptors	Other information
Skin corrosion/irritation	**ES-3: Formulation of the pyrotechnical preparation, filling the delay devices with it, and scraping the top of the powder column before closing each device.**	This is the key exposure scenario. Exposure assessment is based on monitoring/biomonitoring data. The sub-stages, on one side formulation, on the other side filling the delay devices, are closely associated and very similar (same rooms and operators).
	Environmental contributing scenario 1: Formulation in materials (ERC3)	No water is used. Air is filtered. Filters and waste are recovered. See also ES-4.
	Worker contributing scenario 1: HANDLING of solid inorganic substances at ambient temperature (PROC 26)	This contributing scenario takes place in dedicated rooms, aspirations are close to the manipulation points. Filters and waste are recovered. See also ES-4.
	Worker contributing scenario 2: Use as laboratory reagent [SHOOTING for control of performance of the delays] (PROC 15)	Shootings are operated in a 1-meter-square totally enclosed chamber, which is equipped with independant ventilation and filter recovering system.

The generic formulation for the delays is based on four elements: lead chromate ($PbCrO_4$), lead tetroxide[2] (Pb_3O_4), silicon (Si), silicon dioxide (SiO_2). For example, for a 2.8-second delay (the longest duration), two mixtures are introduced into the device, about 1 g each. The scrapping may reduce these quantities somewhat. One composition contents only lead chromate (88%) and silicon compounds. The other has less lead chromate (39%) but also lead tetroxide (48%), and like the first one, silicon compounds. In the end, it can be estimated from the stoichiometry that in 2 grams of composition filled into a 2.8-second delay, there are (Table 13):

- 62.53% of lead (1.251g);
- 10.23% of chromium (0.205 g);
- Indeed, the chromium/lead ratio is 0.1636.

Please note that a 2.8-second delay is only one of the numerous delays in a suitcase and so that in average lead chromate and other constituents may be in smaller quantities. A description of the exact combination of the delays cannot be provided because this information is strategic for the defence of the ships. The total mass of lead chromate is different among the 3 types of suitcases:

- 71.26 g/suitcase type "LEM A",
- 79.83 g/suitcase type "LEM B",
- 31.71 g/suitcase type "LIR E".

[2] *Lead tetroxide (EC number: 215-235-6; CAS number: 1314-41-6) is in "the 6th recommendation for inclusion in the Authorisation List" of ECHA. Please note that this CSR also fully covers this substance, because monitoring is based on lead exposure coming from both constituents of the pyrotechnic preparation, lead chromate and lead tetroxide.*

9.3.1. ES-3 / Environmental contributing scenario 1: Formulation in materials (ERC3) [ERC5 in the IUCLID file]

9.3.1.1. Conditions of use

See next section 9.3.2.

9.3.1.2. Releases

No release is expected as amounts are low, as process is confined to a dedicated room with very performant air aspirations, and as air filters and paper towels used to clean are handled according to ES4 (section 9.4.1).

9.3.1.3. Exposure and risks for the environment and man via the environment

No risk was identified.

9.3.2. ES-3 / Worker contributing scenario 1: HANDLING of solid inorganic substances at ambient temperature (PROC 26)

9.3.2.1. Conditions of use

Formulation of the composition takes place in a dedicated room. This step is conducted under an extractor hood, and the operator is equipped with personal protective equipment (notably gloves and mask). Powders are mixed, and the composition is conditioned in glass bottles. For some details about the formulation, please see in the introduction of this section (9.3).

Filling the delay devices with the composition takes place in two dedicated rooms beside the one in which the composition is prepared. The area has a protected access; operators are trained and have individual protective equipment. Each place has additional polyethylene screen protections to avoid projections; there's an exhaust ventilation with aspirations close to the working points. The delay devices are small metal cylinder, which diameter is less than 3 mm and height a few centimetres (see pictures of the delay devices in Figure 3).

Operations are as follows:

- With a small spoon thin layers of lead chromate composition are introduced into the delays.
- The powder column is compressed with a pneumatic press (Figure 7).
- The delays are then conditioned a waterproof bottle during one month at different temperatures (this is the "aging tests").
- The combustion time of each batch is measured by shooting tests in the dedicated chamber (see next contributing scenario).
- Finally, a scraping operation is needed to adjust the top of the powder column and so the delay duration (Figure 8).
- At the end of this process, delays are sealed with an aluminium sheet and no more exposure is than possible with the devices.

Some exposure can only arise during the manual transfer from the container to the delay cylinder or during scraping, by overflow on surfaces or in suspension in ambient air. Cleaning with acetone-impregnated papers and disposal in yellow boxes is made as described in procedures. General and individual protections are systematically used and air and biological measures are conducted (presented and discussed in section 9.3.3.2).

This scenario is set in a unique site, indoor, and can be described by:

- The use descriptor process category PROC-26 (Handling of solid inorganic substances at ambient temperature - Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, un-packaging, mixing/blending and weighing of metal powders or other minerals);
- The environmental release category ERC3 (Formulation in materials - Mixing or blending of substances which will be physically or chemically bound into or onto a matrix (material) such as plastics additives in master batches or plastic compounds. For instance plasticizers or stabilizers in PVC master-batches or products, crystal growth regulator in photographic films, etc.).

Maximum amounts used during one year are estimated 12 kg and the operators are usually maximum 6 for this stage. However in a conservative approach in this CSR, all 12 workers are considered as exposed under this worst-case scenario assessed through the monitoring data. Work is organised in production campaigns; this point is taken into account for exposure estimations as monitoring data were during peaks of activity. The 12 kg/year is the worst realistic case that may occur in the first years. It should thus be noted that the DAGAIE suitcases production will decline dramatically until the end of supply scheduled no later than 2030, so that the exposure for the whole period is much overestimated.

After the work on the delay devices, each operator cleans the working areas with paper-towels containing a solvent that is mostly acetone. In addition, one specific operator cleans the room, change the filters and handle waste on site (see ES-4 for the waste management stage on site).

Finally, the delays are included in mortars; themselves included in the DAGAIE suitcases (listed in Table 5 as [F-4]: Integration in an ammunition (article)).

Table 12: Conditions of use for Exposure scenario-3 - Worker contributing scenario 1

Parameter	Value	Comment
Product characteristics		
Substance state	Powder	
Substance concentration	100% (Substance as such)	Over substance are added in the delay device, but this depends on the expected time delay. For this risk assessment, it will be considered that the used concentration is always 100%.
Moisture content	< 0.5%	Avoiding moisture and other volatile material is a pyrotechnical specification; when heating the substance at 105°C, the content has to be lower than 0.5% (see annex 2).
Solubility	Very low (< 0.058 mg/l; see table 2)	Volatilisation or aerosol routes are not foreseen
Volatility	Very low volatility (<10^-6 Pa; see table 2)	
Dustiness	Less than 10% are expected under the size 4 µm that can be considered as the "respirable fraction".	See distribution size in table 3 and annex 3.
Amount used, frequency and duration of use		
Annual use on site	≤ 12 Kg/year	Based on the worst case that looks at the decline of the use during the period 2015-2030 and so higher quantities used at the begining of this period (see AoA and figure 6).
Daily use at site	≤ 0.12 Kg/day	The daily may decline, however, that is more the number of days that will decline as a function of supply needs. Daily exposure will be based on the worst measure identified in the monitoring campaigns.
Percentage use at regional scale	100%	Max conservative value.
Number of days with emissions	140 days / year	This is the excact number of days in 2013 and may be decline with supply needs during the period 2015-2030.
Technical and organisational conditions and measures / water		
No water is used in process	0%	Paper-towels are used to clean the working areas and are then considered as hazardous waste.
Technical and organisational conditions and measures / air		
Max release in air of the working zone	< 5% in air	LEV is in place with aspirations very closed to the working areas. Efficientcy is stated as high (> 95%). Monitoring in the working athmosphere show that less than 2.5% (very worst case) of what is used can be in air. Filters are considered as hazardous waste.
Air filters efficiency	> 95%	
Conditions and measures related to treatment of waste (including article waste)		
See exposure scenario 4 / solid hazardous waste		
Other conditions affecting environmental exposure		
See exposure scenario 4 / solid hazardous waste		

Figure 7: Photograph of the management measures for the delay filling operation (ES-3 / Worker contributing scenario 1).

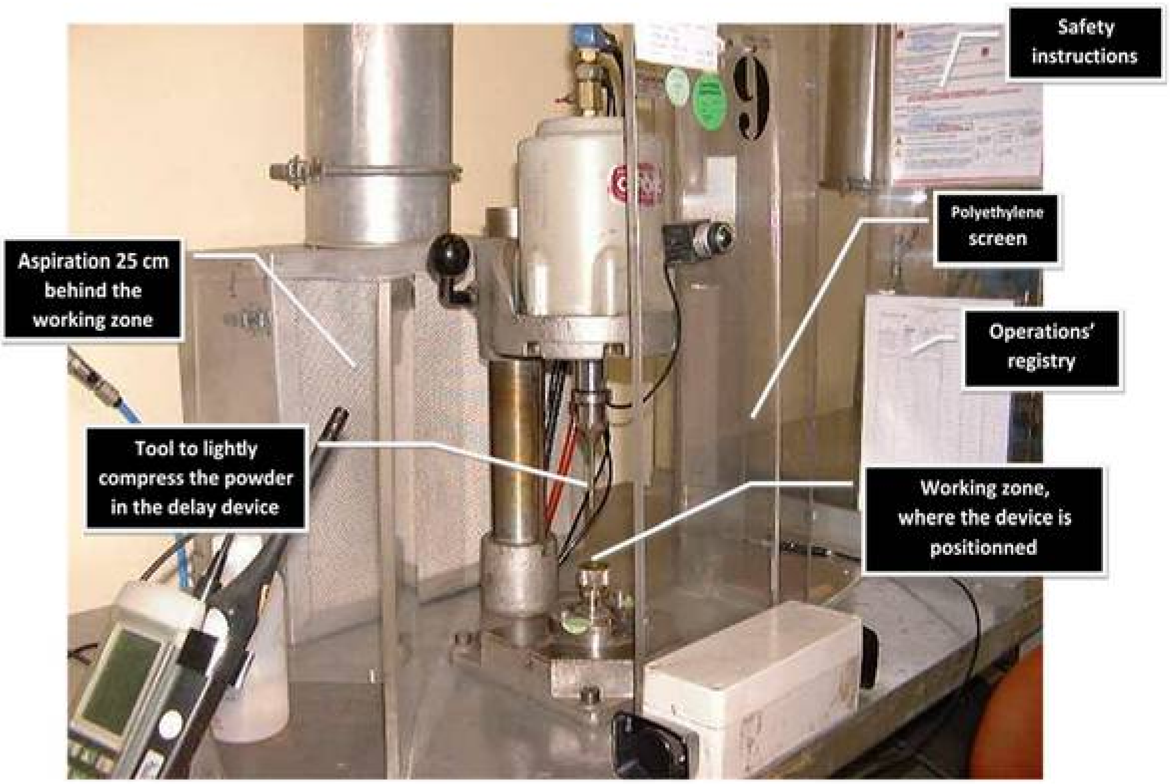
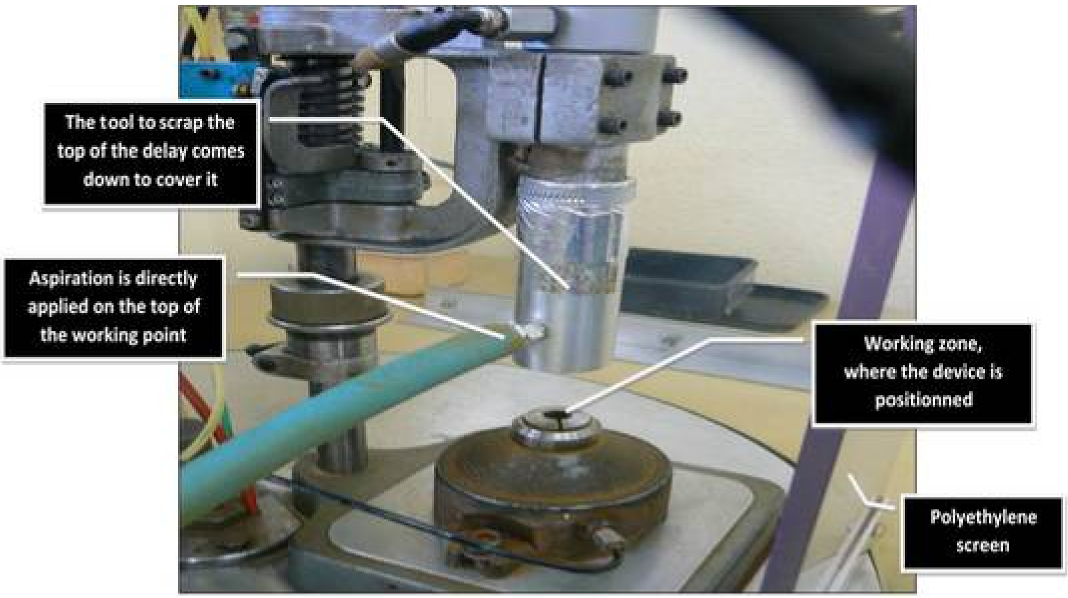


Figure 8: Photograph of the management measures for the delay scraping operation (ES-3 / Worker contributing scenario 1).



9.3.2.2. Exposure and risks for workers

This exposure assessment is based on monitoring data. Monitoring of lead in occupational air is an obligation under the French occupational legislation (articles R4412-27 to R4412-31 and R4412-76 to R4412-80) and the French legislation "décret n°2009-1570 et les arrêtés du 15 décembre 2009 relatifs au contrôle du risque chimique sur les lieux de travail" that are legal texts in line with the European Directives:

- Directive 98/24/EC on risks related to chemical agents at work (CAD);
- Directive 2004/37/EC on carcinogens or mutagens at work (CMD) -. When occupational levels are measured as high, under the same legislation biological monitoring becomes also compulsory.

Lead monitoring in air is obligatory at least through one campaign on 3 operators who conduct one complete working day. Sampling and measures are made by an independent laboratory accredited by COFRAC (recognised by the European co-operation for accreditation). Moreover, LACROIX has a safety management in place and improves the performance continuously to reduce as far as possible the lead chromate exposures. To achieve this goal the air fluxes are measured onto precise points around the working areas in order to place the aspiration tubes in the more efficient way.

What can be easily used to assess exposures are the air monitoring data generated by the external laboratory, which is moreover accredited COFRAC. In contrast, the analysis of the biological monitoring data is less easy to interpret because 1) of the very small number of workers (4 to 6, maximum 12), 2) the individual backgrounds, and 3) the plan of an occupational practitioner that order biological monitoring according to air measures' results. Thus, in this CSR the lead monitoring in occupational air from the year 2013, the last available at the time of this risk assessment report, appears as the best representation of the exposure scheme – worst case - expected during the period 2015-2030. Biological monitoring data will also be presented in this CSR in support of the conclusions made with the air monitoring data. The full report of the monitoring data of year 2013 is attached as the confidential Annex 7. Hereafter, the data of this monitoring are analysed (Table 15; Table 16). Biological monitoring data are more scattered, but analysis over 3 years, shows that the mean blood concentrations, without any correction for the background lead exposures, is maximum 76.83 µg/L. The biological values are so below the French and international OELs (Figure 9). Elsewhere, to also estimate the chromium exposures in 2013, the ratio Chromium/lead was used:

- The stoichiometry of the composition shows that the ratio Cr/Pb is 0.1636 (Table 14).
- The campaigns in the years 2008 and 2009, during which some measures in air were made at the same time on lead and chromium, showed:
  - a mean ratio Cr/Pb equal to 0.1207;
  - a maximum ratio equal to 0.3231 (Table 14).

In a conservative approach, the maximum value 0.3231 is used. Indeed, conclusions made with the air lead monitoring data of 2013 (Table 15) and by using Cr/Pb ratio of the campaigns 2008/2009 to estimate the air chromium concentrations (Table 16), will be used to assess the risks and estimate the costs in the SEA:

- Lead exposure during use-1 represented by ES-3: 0.006 mg Pb / m^3 air;
- Chromium exposure during use-1 represented by ES-3: by inhalation 0.0019 mg Cr / m^3 air and by the swallowing route 0.0001 mg Cr/kg bw/day.

Table 13: Cr/Pb ratio calculated from lead chromate + lead tetroxide composition in delay devices.

Cr/Pb ratio calculated from stoichiometry of the preparation in the delay ≈ 2 grams of preparation	g	fraction
PbCrO4	1.27E+00	6.36E-01
Pb3O4	4.80E-01	2.40E-01
Pb	1.25E+00	6.25E-01
Cr	2.05E-01	1.02E-01
Si	2.33E-01	1.17E-01
O	3.07E-01	1.54E-01
Cr + Pb + Si	1.69E+00	8.46E-01
Cr/Pb		**0.1636**

This table shows the calculation of the chromium/lead ratio by using the proportions of lead chromate and lead tetroxide used in the pyrotechnical composition.

Table 14: Cr/Pb ratio calculated from air monitoring campaigns 2008/2009

Cr/Pb ratio calculated from air monitoring campaigns 2008/2009	per Operator			Statistical values		
	d	e	f	Mean	±	**Max**
Pb mg/m^3 (campaigns 2008/2009)	2.07E-02	6.50E-03	3.51E-02			
Cr mg/m^3 (campaigns 2008/2009)	6.00E-04	2.10E-03	3.50E-04			
Ratio Cr/Pb from the campaign 2008/2009	0.0290	0.3231	0.0100	**0.1207**	0.1349	**0.3231**

This table shows the calculation of the chromium/lead ratio by using the proportions of lead and chromium measured in the occupational air.

Table 15: Occupational Lead exposures during ES-3 (year 2013).

Pb Exposures / Air monitoring 2013 (PbCrO4 + Pb3O4)	per Operator			Statistical values		
	a	b	c	Mean	±	**Max**
Weight of Pb (mg)	0.00432	0.02960	0.02050			
Air volume sampled (m^3)	0.721	0.780	0.726			
Raw measures: Pb mg/m^3	0.006	0.038	0.028	0.024	0.012	**0.038**
Duration of the work (minutes)	465	465	465			
Duration of a standard 8H work (minutes)	480	480	480			
Pb mg/m^3 adjusted to 8 hours	0.006	0.039	0.029	0.025	0.012	**0.039**
"Respirable fraction" ≤ 4.9 µm (for information)	0.100	0.100	0.100			
"Respirable fraction" ≤ 14.78 µm (this value will be used to add margin of precaution)	0.500	0.500	0.500			
Pb mg/m^3 adjusted to 8 hours and by taking into account the "respirable fraction"	0.003	0.020	0.015	0.012	0.006	**0.020**
Duration with Mask (%)	77.4	77.4	77.4			
Protection factor with Mask	10	10	10			
Pb mg/m^3 adjusted to 8 hours and taking into account "respirable fraction" & mask protection	0.001	0.006	0.004	0.004	0.002	**0.006**

Table 16: Occupational Chromium exposures during ES-3 (year 2013).

Cr exposures in 2013 (PbCrO4 + Pb3O4)	per Operator			Statistical values		
	a	b	c	Mean	±	**Max**
Ratio Cr/Pb from the stoichiometry of the preparation (see table-12)	0.1636	0.1636	0.1636			
Cr(VI) mg/m^3 calculated from the stoichiometry, adjusted 8 hours, taking into account respirable fraction a	1.53E-04	9.72E-04	7.23E-04	0.0006	0.0003	**0.0010**
Cr(VI) mg/kg bw/day & by considering that 50% of the respirable fraction is swallowed	1.10E-05	6.94E-05	5.16E-05	0.0000	0.0000	**0.0001**
Mean ratio Cr/Pb from the campaigns 2008/2009 (see table-13)	0.1207	0.1207	0.1207			
Cr(VI) mg/m^3 calculated from the mean ratio Cr/Pb	1.13E-04	7.17E-04	5.33E-04	0.0005	0.0002	**0.0007**
Cr(VI) mg/kg bw/day & by considering that 50% of the respirable fraction is swallowed	8.08E-06	5.12E-05	3.81E-05	0.0000	0.0000	**0.0001**
Max ratio Cr/Pb from the campaigns 2008/2009 (see table-13)	0.3231	0.3231	0.3231			
Cr(VI) mg/m^3 calculated from the max ratio Cr/Pb	3.03E-04	1.92E-03	1.43E-03	0.0012	0.0006	**0.0019**
Cr(VI) mg/kg bw/day & by considering that 50% of the respirable fraction is swallowed	2.16E-05	1.37E-04	1.02E-04	0.0001	0.0000	**0.0001**

From the comparison of these exposures to the OEL proposed for lead by NIOSH (1992), it can be concluded that:

- RCR Pb (in $PbCrO_4$ + Pb_3O_4) = max Pb mg/m^3 adjusted to 8 hours and taking into account "respirable fraction" & mask protection / NIOSH OEL 10H-TWA (Pb mg/m^3) = **0.119**.

From the comparison of these exposure figures to the OEL proposed for chromium in lead chromate by ACGIH (2014), it can be concluded that:

- RCR Cr (in $PbCrO_4$) = max Pb mg/m^3 adjusted to 8 hours and taking into account "respirable fraction" & mask protection / ACGIH OEL 8H-TWA specifically for $PbCrO_4$ (Cr mg/m^3) = **0.160**.
- Please note that for this RCR approach, the split of the exposure fraction into the two routes, on one side the respiratory tract, on the other side the digestive tract, was not calculated. This approach is conservative, as absorption may be higher at the alveolar level than at the intestinal wall level.

From the RCR calculated on one hand for lead exposure, on the other hand for chromium exposure, it can be estimated the aggregated RCR:

- Aggregated RCR (Pb + Cr in $PbCrO_4$ and Pb_3O_4) = RCR Pb + RCR Cr = **0.279**.

This aggregated RCR, which covers both counterparts of lead chromate, lead and chromium, is below 1. This value is an indication that exposures may be considered as acceptable. However, LACROIX takes full consideration of the risks that may come from non-threshold effects of chromium. Therefore, the chosen approach in this CSR is to consider that risks are controlled under the acceptable threshold for the lead counterpart; but that an excess risks has to be estimated to assess in SEA the possible impacts of exposures to chromium. Please see section 10 for excess risks calculations.

Figure 9: Lead biomonitoring (years 2012/2013/2014)

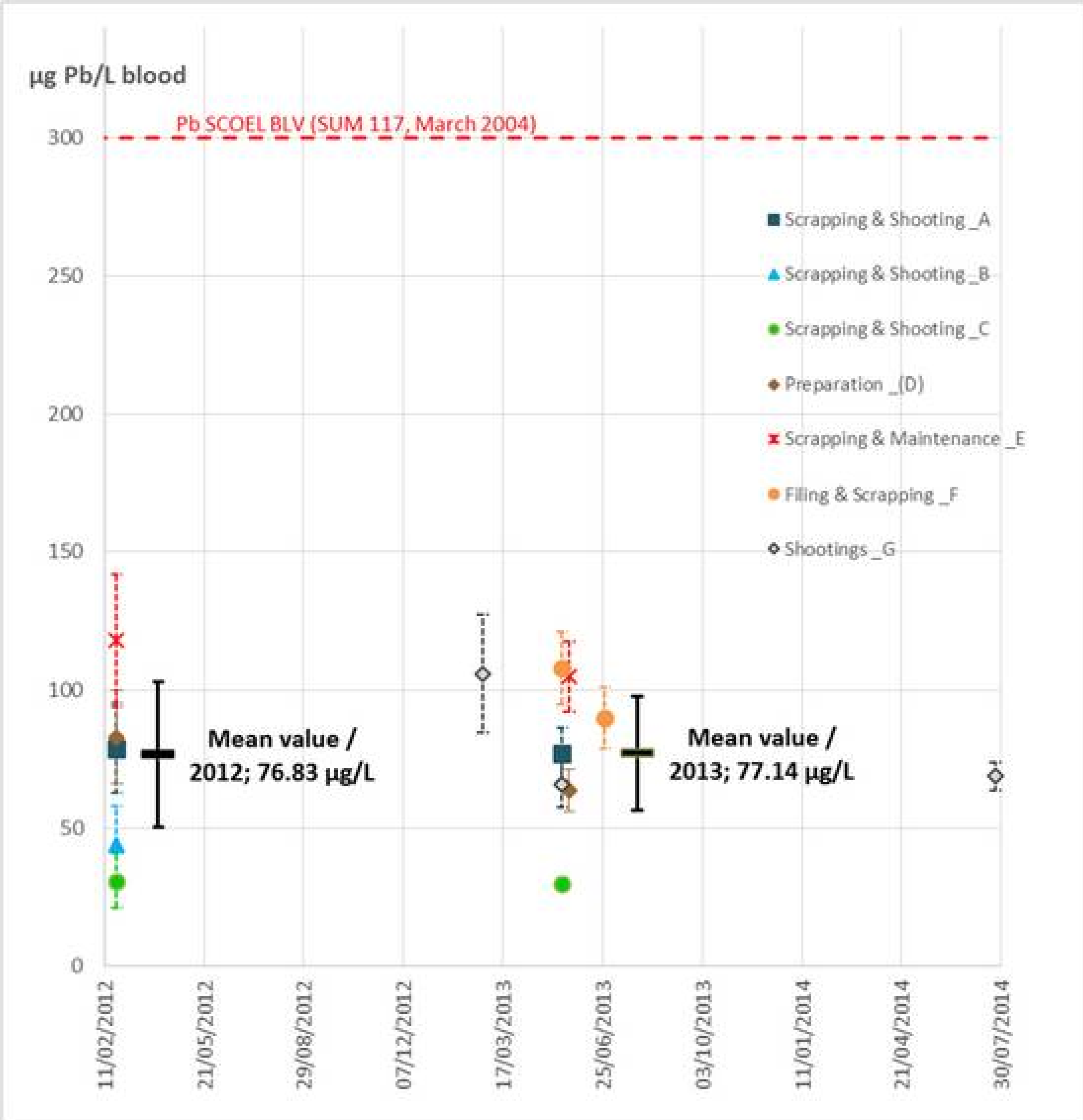


Table 17: RCR for exposures to the lead contained in lead chromate + lead tetroxide.

Pb RCR / Air monitoring 2013 (PbCrO4 + Pb3O4)	per Operator			Statistical values		
	a	b	c	Mean	±	Max
French OEL ("VLEP", 2006) 8H-TWA (Pb mg/m^3)	0.100	0.100	0.100			
RCR with reference to the French OEL for Pb	0.009	0.059	0.044	0.038	0.019	0.059
NIOSH OEL 10H-TWA (1992) (Pb mg/m^3) [used as if 8H-TWA]	0.050	0.050	0.050			
RCR with reference to the NIOSH OEL for Pb	**0.019**	**0.119**	**0.088**	0.075	0.038	**0.119**

Table 18: RCR for exposures to the chromium contained in lead chromate.

Cr RCR / Pb Air monitoring 2013	per Operator			Statistical values		
	a	b	c	Mean	±	Max
NIOSH OEL 8H-TWA (2013) for Chromium and chromium compounds	0.0002	0.0002	0.0002			
~~RCR with reference to the NIOSH OEL for Cr in Chromium compounds~~	~~1.515~~	~~9.594~~	~~7.139~~	~~6.082~~	~~3.045~~	~~9.594~~
ACGIH OEL 8H-TWA (2014) specifically for PbCrO4 (Cr mg/m^3)	0.012	0.012	0.012			
RCR with reference to the ACGIH OEL for Cr in PbCrO4	0.025	0.160	0.119	0.101	0.051	**0.160**

Note: For transparency, the NIOSH value is shown. However, the ACGIH value was chosen is this CSR because it is specifically designed for lead chromate (which is notably less soluble in water than other chromate and chromium compounds).

Table 19: Aggregated RCR values for Lead and Chromium in Lead chromate + Lead tetroxide.

PbCrO4 + Pb304 RCR	per Operator			Statistical values		
	a	b	c	Mean	±	Max
RCR with reference to the NIOSH OEL for Pb	1.88E-02	1.19E-01	8.84E-02	0.075	0.038	**0.119**
RCR with reference to the ACGIH OEL for Cr in PbCrO4	2.52E-02	1.60E-01	1.19E-01	0.101	0.051	**0.160**
Aggregated RCR	4.40E-02	2.79E-01	2.07E-01	0.177	0.088	**0.279**

9.3.3. ES-3 / Worker contributing scenario 2: Use as laboratory reagent [SHOOTING for control of performance of the delays] (PROC 15)

Beside ES-3 / contributing scenario 1 (Formulation of the pyrotechnical composition, filling the delay devices with it, and scraping the top of the powder column before closing each device), shooting tests are required to control the performance of the delays' batches.

9.3.3.1. Conditions of use

One pyrotechnic operator tests 100-1000 delays per year (mean = 550 tests). These tests are conducted in a dedicated and entirely enclosed one-square-meter chamber with its own filtration system. The operator spends only several minutes per test, and alternate with the main work that is ES-3 / contributing scenario 1. The test chamber is totally confined during the shooting. The operator does not stay in the room, and an independent aspiration system cleans the chamber before its opening. Indeed, emissions from a few delays equivalent to a few grams per day and in a closed system can be considered as lower or at least equivalent to the exposure during the main task. This contributing scenario is described by PROC 15 (Use as laboratory reagent).

9.3.3.2. Exposure and risks for workers

Because the times of these tests are short and the testing chamber is closed, exposures appear as less significant than for the principal activity. Workers may be exposed during the removing of the dust from the chamber. However, monitoring data show that values are very lower than or at least equivalent to the exposures in the room where composition is made and delays filled (Annex 7). There is no need to develop specific exposure estimations as this contributing scenario is covered by the time estimations of the principal activity, which is formulation of lead chromate composition and filling the delay devices with it.

Hereafter is however described an attempt to estimate the proportion of lead that may be recovered or released from a delay. This is a reference in the discussions about the waste management on the site of LACROIX (ES-4) and the shootings on Navies" ships (ES-5).

In a shooting test, it was measured that about 99.44% of the initial composition mass is recovered as slag in the bottom of the device. However, this value should be used with precautions as the vitrification state in the device is not well understood. One way to improve the picture was to analyse by ICP-OES lead and chromium content in slags (ETIENNE LACROIX TOUS ARTIFICES SA had the will to be transparent. Therefore, all contents of this document are not confidential, except some annexes.

For the annexes that should be considered as confidential, the title of the annex includes the term "CONFIDENTIAL" and just below the title a justification is brought in a short paragraph entitled "justification for confidentiality".

Annex 1); proportions were found as follows:

- 54.90% of lead;
- 1.13% of chromium.

Crossing proportions with the estimated weights recovered in the device leads the conclusion that:

- 87.3 % of lead and 11.0% of chromium are recovered in the device,
- 12.7% of lead and 89.0% of chromium are released from the device.

The releases from the device during the shooting test are confined in the test chamber. Elsewhere, when devices are included in ammunition, themselves included in the DAGAIE suitcases, these releases from the devices do not mean that there are equivalent releases outside the system during the use of the DAGAIE system.

Table 20: Estimations of the fractions of Lead and Chromium released from the device after a shooting in a dedicated pyrotechnic test chamber (example of a 2.8s delay device).

Before shooting		
Empty device	2.9130	g
disc + detonator	0.2122	g
Total initial mass of the device without the preparation	*3.1252*	*g*
Total initial mass of the device with the preparation	3.5542	g
Estimated Mass of preparation	0.4290	g
Pb content (based on stoichometry of the preparation)	62.53	%
Pb mass	**0.2683**	**g**
Cr content (based on stoichometry of the preparation)	10.23	%
Cr mass	**0.0439**	**g**
After shooting		
Mass of the device with the products of the shooting	**3.5293**	**g**
Correction of the initial mass of the device / 90% loss of the detonator	*3.1027*	*g*
Estimated mass of slag in the device after the shooting	**0.4266**	**g**
Estimated fraction of slag	**0.9944**	**%**
Pb content (based on ICP-OES anlysis)	54.90	%
Pb mass	**0.2342**	**g**
Cr content (based on ICP-OES anlysis)	1.13	%
Cr mass	**0.0048**	**g**
Estimated Pb recovered in device	**87.3**	%
Estimated Pb released from device	**12.7**	**%**
Estimated Cr recovered in device	**11.0**	%
Estimated Cr released from device	**89.0**	**%**

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

Risk for workers is only on LACROIX' site where lead chromate is formulate into delay devices. In order to maximise the conservative approach, even some workers work only a few hours per year directly for this activity, it was chosen to use the worst exposure scenario ES-3 for the 12 workers. In addition, exposures were based on the worst concentration measured in occupational air during this scenario.

As "RAC/27/2013/06-Rev.1" document of ECHA was agreed during RAC-27 and proposes for workers the values 4 ± 10^{-3} excess lifetime lung cancer mortality risk per µg Cr(VI)/m^3 and 2.0 ± 10^{-4} excess lifetime intestinal cancer risk per µg Cr(VI)/m^3, it appears as not necessary to develop all the discussions about the health hazard assessment of lead chromate, and rather to directly used this excess risk values to weight the impact of the "use scenario" if Authorisation is granted. Please note that several assumptions are in favour of a conservative approach in the case of lead chromate and this specific use of LACROIX (see all the details in exposure and carcinogenicity sections, as in AoA).

The mean age of the maximum-12 workers being 52.6 years old, no pregnancy is expected among these workers until the end of the use of lead chromate if Authorisation is granted. Furthermore, the biological monitoring indicates that exposure concentration in air are lower than the reference toxicological values (see full details in part 9.2). Thus, no risk for developmental toxicity or fertility has to be taken into account in this CSR, and economically weighted in the SEA.

Finally, using the monitoring data, the excess risks' values proposed by RAC, and including a correction to take into account that use was 7.6 kg in 2013 and will be in average 8.7 kg/year[3] during the period 2015-2030, the excess risks for lung and small intestine cancer can be proposed as follows (Table 21 and Table 22):

- Maximum Excess lifetime lung cancer mortality risk per 01 worker for use-1 during the period 2015-2030 = $1.40*10^{-6}$
- Maximum Excess lifetime lung cancer mortality risk per 12 worker for use-1 during the period 2015-2030 = $1.68*10^{-5}$
- Maximum Excess lifetime small intestine cancer risk per 01 worker for use-1 during the period 2015-2030 = $5.01*10^{-9}$
- Maximum Excess lifetime small intestine cancer risk per 12 worker for use-1 during the period 2015-2030 = $6.01*10^{-8}$

[3] *If the maximum value 12 kg/year is used, this would mean that the total use during the 15 years is 156 kg. As this is not true because the remaining stock of lead chromate is only 130 kg, the mean annual use is the appropriate value to predict the excess risks during the period 2015-2030.*

Table 21: Excess risk associated to the use-1 of lead chromate during the period 2015-2030 – lung cancer.

Excess cancer risks associated to the use of PbCrO4	per Operator			Statistical values		
Statement: excess risks appear as of the first µg chromium exposure	a	b	c	Mean	±	Max
Excess lifetime lung cancer mortality risk per µg Cr(VI)/m^3 (40 year working life - 8h/d - 5d/w) / RAC/27/2013/06rev1 (ECHA, 2013)	**4.00E-03**	**4.00E-03**	**4.00E-03**			
1. Ref. to RAC's conditions	70400	70400	70400			
Excess lifetime lung cancer mortality risk per µg Cr(VI)/m^3 per worker _ as if use-1 = 40years/1760hours(220days/8hours)	4.00E-03	4.00E-03	4.00E-03			
Excess lifetime lung cancer mortality risk per 1 worker per year	8.08E-08	5.12E-07	3.81E-07	3.24E-07	1.62E-07	5.12E-07
Excess lifetime lung cancer mortality risk per 12 workers per year	9.69E-07	6.14E-06	4.57E-06	3.89E-06	1.95E-06	6.14E-06
Excess lifetime lung cancer mortality risk per 1 worker per 15 years	1.21E-06	7.68E-06	5.71E-06	4.87E-06	2.44E-06	7.68E-06
Prediction of excess lifetime lung cancer risk for 1 worker during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	1.39E-06	8.79E-06	6.54E-06	5.57E-06	2.79E-06	8.79E-06
Excess lifetime lung cancer mortality risk per 12 workers per 15 years	1.45E-05	9.21E-05	6.85E-05	5.84E-05	2.92E-05	9.21E-05
Prediction of excess lifetime lung cancer risk for 12 workers during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	1.66E-05	1.05E-04	7.85E-05	6.68E-05	3.35E-05	1.05E-04
2. Ref. to 1760hours/year * 15 years / use-1	29960	29960	29960			
Excess lifetime lung cancer mortality risk per µg Cr(VI)/m^3 per worker _ as if use-1 = 15years/1760hours(220days/8hours)	1.70E-03	1.70E-03	1.70E-03			
Excess lifetime lung cancer mortality risk per 1 worker per year	3.44E-08	2.18E-07	1.62E-07	1.38E-07	6.91E-08	2.18E-07
Excess lifetime lung cancer mortality risk per 12 workers per year	4.13E-07	2.61E-06	1.94E-06	1.66E-06	8.29E-07	2.61E-06
Excess lifetime lung cancer mortality risk per 1 worker per 15 years	5.16E-07	3.27E-06	2.43E-06	2.07E-06	1.04E-06	3.27E-06
Prediction of excess lifetime lung cancer risk for 1 worker during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	5.90E-07	3.74E-06	2.78E-06	2.37E-06	1.19E-06	3.74E-06
Excess lifetime lung cancer mortality risk per 12 workers per 15 years	6.19E-06	3.92E-05	2.92E-05	2.48E-05	1.24E-05	3.92E-05
Prediction of excess lifetime lung cancer risk for 12 workers during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	7.08E-06	4.49E-05	3.34E-05	2.84E-05	1.42E-05	4.49E-05
3. Ref. to 749hours/year during 15 years / use-1	11235	11235	11235			
Excess lifetime lung cancer mortality risk per µg Cr(VI)/m^3 per worker _ use-1 = 15years/749hours(max)	6.38E-04	6.38E-04	6.38E-04			
Excess lifetime lung cancer mortality risk per 1 worker per year	1.29E-08	8.17E-08	6.08E-08	5.18E-08	2.59E-08	8.17E-08
Excess lifetime lung cancer mortality risk per 12 workers per year	1.55E-07	9.80E-07	7.29E-07	6.21E-07	3.11E-07	9.80E-07
Excess lifetime lung cancer mortality risk per 1 worker per 15 years	1.93E-07	1.22E-06	9.11E-07	7.77E-07	3.89E-07	1.22E-06
Prediction of excess lifetime lung cancer risk for 1 worker during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	2.21E-07	1.40E-06	1.04E-06	8.89E-07	4.45E-07	**1.40E-06**
Excess lifetime lung cancer mortality risk per 12 workers per 15 years	2.32E-06	1.47E-05	1.09E-05	9.32E-06	4.67E-06	1.47E-05
Prediction of excess lifetime lung cancer risk for 12 workers during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	2.66E-06	1.68E-05	1.25E-05	1.07E-05	5.34E-06	**1.68E-05**

Note: the mean use value 8.7 kg/year was used, because excess risks are proportional to the whole amount used during the period, 130 kg (8.7kg*15years=130kg). If the maximum value 12 kg/year had been used, the calculated excess risks would have represented the excess risks associated to (12kg*15years=180kg).

This table summarises the calculation by using 3 steps towards the real excess risk of lung cancer mortality if use-1 is authorised during the period 2015-2030:

- During an entire work life (values of RAC are reported for this context);
- During 15 years work (period requested in this Authorisation application);
- During 15 years work and by taking into account the maximum hours work per year (use-1).

Table 22: Excess risk associated to the use-1 of lead chromate during the period 2015-2030 – small intestine cancer

Excess cancer risks associated to the use of PbCrO4	per Operator			Statistical values		
Statement: excess risks appear as of the first µg chromium exposure	a	b	c	Mean	±	**Max**
Excess lifetime small intestine cancer risk per µg Cr(VI)/kg bw/day (40 year working life - 8h/d - 5d/w) / RAC/27/2013/06rev1 (ECHA, 2013)	**2.00E-04**	**2.00E-04**	**2.00E-04**			
1. Ref. to RAC's conditions	70400	70400	70400			
Excess lifetime small intestine cancer mortality per µg Cr(VI)/kg bw/day per worker _ as if use-1 = 40years/1760hours(220days/8hours)	2.00E-04	2.00E-04	2.00E-04			
Excess lifetime small intestine cancer risk per 1 worker per year	2.89E-10	1.83E-09	1.36E-09	1.16E-09	5.80E-10	1.83E-09
Excess lifetime small intestine cancer risk per 12 workers per year	3.46E-09	2.19E-08	1.63E-08	1.39E-08	6.96E-09	2.19E-08
Excess lifetime small intestine cancer risk per 1 worker per 15 years	4.33E-09	2.74E-08	2.04E-08	1.74E-08	8.70E-09	2.74E-08
Prediction of excess lifetime lung cancer risk for 1 worker during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	4.95E-09	3.14E-08	2.33E-08	1.99E-08	9.96E-09	3.14E-08
Excess lifetime small intestine cancer risk per 12 workers per 15 years	5.19E-08	3.29E-07	2.45E-07	2.09E-07	1.04E-07	3.29E-07
Prediction of excess lifetime lung cancer risk for 12 workers during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	5.95E-08	3.77E-07	2.80E-07	2.39E-07	1.20E-07	3.77E-07
2. Ref. to 1760hours/year * 15 years / use-1	29960	29960	29960			
Excess lifetime small intestine cancer risk per µg Cr(VI)/kg bw/day per worker _ as if use-1 = 15years/1760hours(220days/8hours)	8.51E-05	8.51E-05	8.51E-05			
Excess lifetime small intestine cancer risk per 1 worker per year	1.23E-10	7.78E-10	5.79E-10	4.93E-10	2.47E-10	7.78E-10
Excess lifetime small intestine cancer risk per 12 workers per year	1.47E-09	9.33E-09	6.94E-09	5.92E-09	2.96E-09	9.33E-09
Excess lifetime small intestine cancer risk per 1 worker per 15 years	1.84E-09	1.17E-08	8.68E-09	7.40E-09	3.70E-09	1.17E-08
Prediction of excess lifetime lung cancer risk for 1 worker during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	2.11E-09	1.34E-08	9.94E-09	8.47E-09	4.24E-09	1.34E-08
Excess lifetime small intestine cancer risk per 12 workers per 15 years	2.21E-08	1.40E-07	1.04E-07	8.87E-08	4.44E-08	1.40E-07
Prediction of excess lifetime lung cancer risk for 12 workers during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	2.53E-08	1.60E-07	1.19E-07	1.02E-07	5.09E-08	1.60E-07
3. Ref. to 749hours/year during 15 years / use-1	11235	11235	11235			
Excess lifetime small intestine cancer risk per µg Cr(VI)/kg bw/day per worker _ use-1 = 15years/749hours(max)	3.19E-05	3.19E-05	3.19E-05			
Excess lifetime small intestine cancer risk per 1 worker per year	4.60E-11	2.92E-10	2.17E-10	1.85E-10	9.26E-11	2.92E-10
Excess lifetime small intestine cancer risk per 12 workers per year	5.53E-10	3.50E-09	2.60E-09	2.22E-09	1.11E-09	3.50E-09
Excess lifetime small intestine cancer risk per 1 worker per 15 years	6.91E-10	4.37E-09	3.25E-09	2.77E-09	1.39E-09	4.37E-09
Prediction of excess lifetime lung cancer risk for 1 worker during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	7.91E-10	5.01E-09	3.73E-09	3.17E-09	1.59E-09	**5.01E-09**
Excess lifetime small intestine cancer risk per 12 workers per 15 years	8.29E-09	5.25E-08	3.91E-08	3.33E-08	1.67E-08	5.25E-08
Prediction of excess lifetime lung cancer risk for 12 workers during 15 years, by taking into account that monitoring is for 7.6 kg/year in 2013 and that mean use will be 8.7 kg/year during the period 2015-2030.	9.49E-09	6.01E-08	4.47E-08	3.81E-08	1.91E-08	**6.01E-08**

Note: the mean use value 8.7 kg/year was used, because excess risks are proportional to the whole amount used during the period, 130 kg (8.7kg*15years=130kg). If the maximum value 12 kg/year had been used, the calculated excess risks would have represented the excess risks associated to (12kg*15years=180kg).

This table summarises the calculation by using 3 steps towards the real excess risk of small intestine cancer if use-1 is authorised during the period 2015-2030:

- During an entire work life (values of RAC are reported for this context);
- During 15 years work (period requested in this Authorisation application);
- During 15 years work and by taking into account the maximum hours work per year (use-1).

10.1.2. Consumers

Not relevant.

10.2. Environment (combined for all emission sources)

Not relevant.

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

10.2.1.2. Regional exposure

10.2.1.3. Local exposure due to all wide dispersive uses