TRISODIUM HEXAFLUOROALUMINATE

(Cryolite)

CAS No: 13775-53-6

EINECS No: 237-410-6

CAS No: 15096-52-3

EINECS No: 237-410-6

(3rd Priority List)

Strategy For Limiting Risks

Human Health

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CONTENT

0 Summary

Trisodium hexafluoroaluminate (Cryolite) is produced at four sites in the EU-15. In 2006 the production volume of these four sites was 23,561 t/a of which 11,500 t/a were exported. The volume for the European market was thus 12,061 t/a. Production capacity was provided by three companies and it makes 43,200 t/a.

Synthetic cryolite can be obtained by reaction of hydrofluoric acid with aluminium hydroxide to form fluoroaluminium acid. After treating H_3AlF_6 with NaCl cryolite precipitates. In addition, H_2SiF_6 can be used as starting material in a similar reaction where the precipitated silicic acid is separated from the reaction solution.

Cryolite is the main constituent of the electrolytic bath in the production of aluminium. During the electrolytic process cryolite is also formed as a by-product. EAA has provided an estimate of 24,000 t/a cryolite in the excess bath material produced at the European aluminium smelter sites.

The main volume of intentionally produced cryolite is used as bath material in aluminium smelters. Cryolite is also used as filler in synthetic resins for abrasives and as binding agent for cutting or grinding discs. Minor uses are the use as opacifier in glass and enamel industry, in pyrotechnics and in ceramic industry.

The classification of trisodium hexafluoroaluminate (cryolite) according to Annex I of Directive 67/548/EEC (24th ATP (98/73/EC), Index number: 009-016-00-2):

T; R48/23/25 – Xn; R20/22 – N; R51-53.

The following proposal for a harmonised classification and labelling was laid down in an Annex XV –Dossier:

Proposed classification based on Directive 67/548/EEC:

T; R48/23/25 – Xn; R20 – Xi; R36 - Repr.Cat.3; R63.

Workers

It has been concluded from the risk assessment that there is a need for limiting the risks due to repeated dose toxicity (local and systemic effects), and developmental toxicity. On the background of local effects in the airways air concentrations of cryolite dust at the workplace should be controlled to a level in the range of 0.1 mg/m^3 (critical exposure level for local effects after repeated exposure). In doing so also inhalation risks from other endpoints, especially systemic effects by fluorosis as result of repeated exposure and developmental toxicity are similarly and effectively mitigated.

Special attention should be given to skin contact. The most critical effect again is repeated doses systemic toxicity (fluorosis). The critical exposure level is 92 mg/person/day (1.3 mg/kg/day). In the assessment it was assumend that 10% of cryolite is absorbed through the skin. Considerable (but still practical) effort has to be taken within the framework of workeplace legislation, in order to achieve the proposed level of dermal exposure. Dermal risk estimation might be refined by an additional suitable dermal absorption study.

The risk reduction strategy recommends the following measures:

- to establish at Community level occupational exposure limit values for cryolite according to Directive 98/24/EEC

- information on the need of technical and organisational measures, specific training, and occupational hygiene on company level in the framework of Directive 98/24 in order to reduce dermal exposure in scenario 1, 3 and 4.

1 Background

In the framework of EU Regulation 793/93 on the evaluation and control of the risks of existing substances data are gathered, priority substances are selected, their risks are assessed and, if necessary, strategies for limiting the risks are developed. The risk assessments cover the risks to man exposed directly at the workplace or as a consumer and indirectly through the environment and the risks to the environment. Trisodium hexafluoroaluminate (Cryolite) is a substance on the third priority list (Regulation (EC) No. 143/97 of the Commission of 27 January 1997).

Cryolite is the double fluoride of sodium and aluminium (Na_3AlF_6) with a melting point of about 1010°C. Natural cryolite (CAS No.: 15096-52-3) has been found in substantial quantities only in Greenland but it is practically exhausted and abandoned in favour of synthetic cryolite (CAS No.: 13775-53-6). Synthetic cryolite is a white crystalline solid at room temperature. The Relative density is 2.95 at 20 °C, the Vapour pressure is 2.5 mbar (= 250 Pa) at 1027 °C. The water solubility of cryolite is rather low: 0.41 g/l at 25 °C (pH unknown) and 0.9 g/l at 20 °C (pH 4 – 7).

Production processes

Synthetic cryolite can be obtained by reaction of hydrofluoric acid with aluminium hydroxide to form fluoroaluminium acid. After treating H_3AlF_6 with NaCl cryolite precipitates:

$$6HF + Al(OH)_3 \rightarrow H_3AlF_6 + 3H_2O$$

$$H_3AlF_6 + NaCl \rightarrow Na_3AlF_6 + 3HCl$$

In addition, H_2SiF_6 can be used as starting material in a similar reaction where the precipitated silicic acid is separated from the reaction solution:

$$H_2SiF_6 + 2\ Al(OH)_3 \rightarrow 2\ AlF_3 + SiO_2 + 4\ H_2O$$

$$2\ AlF_3 + 6\ NaCl \rightarrow 2\ Na_3AlF_6 + 6\ HCl$$

Cryolite is put on the market according to the producers in powder form. No information on the size of the particles was provided with the exception of the use of words “grinded”, “granular”, “flour“ and “fine” to distinguish different particle sizes.

Natural cryolite (CAS 15096-52-3) was extensively mined in the early 20th century with substantial amounts found in Greenland and smaller ores in Russia and US. Today natural sources are essentially exhausted and synthetic cryolite is used instead (Ullmann's, 1985; Römpp, 1997).

Cryolite is the main constituent of the electrolytic bath in the production of aluminium. During the electrolytic process cryolite is also formed as a by-product. Alumina (calcinated metallurgical grade Al_2O_3), the raw material of aluminium, contains normally 0.2 – 0.5 % Na_2O w/w which reacts with aluminium fluoride present in the electrolytic bath:

$$3\ Na_2O + 4\ AlF_3 \rightarrow 2\ AlF_3 \cdot 3\ NaF + Al_2O_3$$

This reaction is separate from the reduction reaction of alumina to aluminium in Hall-Héroult process, which is the only smelting process used today industrially. Based on the molar masses of Na_2O and cryolite, approximately 2 times the mass of Na_2O of excess cryolite results, if no other sources of sodium are available and if losses of cryolite are excluded. In this case, one tonne of alumina fed to the process would produce normally ca. 4-10 kg excess cryolite. According to EAA (2007a), two tonnes of alumina is reduced to one tonne of aluminium. Hence, one tonne of primary aluminium is based on the assumptions above accompanied by ca. 8-20 kg (0.8-2 % w/w) of excess cryolite as by-product.

In modern smelters excess bath material is tapped from time to time. Concentrations of bath components vary within and between the sites depending on the alumina quality, other substances are added to the bath and on other process parameters. An example of the contents of bath material has been provided by Alcoa (Solvay, 2007):

Cryolite	51-53 %
Al_2O_3	45 % (WS: insoluble or < 1 mg/l according to IUCLID
AlF_3	7 % (WS: 5.3-9.4 at pH 5.9, European Commission, 2008)
CaF_2	3 %
MgF_2	1.2 %
Carbon	0.8 %
Fe_2O_3	0.27 %
SiO_2	0.25 %
Moisture	0.25 % (Rapporteur assumes H_2O is meant by this)

It is noted, that the Rapporteur considers that bath material has another identity than cryolite. Already based on the very low water solubility of the substantial constituent Al_2O_3, properties of cryolite do not resemble the properties of bath material.

Production capacity and tonnage

Intended production

Cryolite is produced at four sites in the EU-15. All sites provided information on exposure. Sites 2, 3 and 4 updated their information in 2006. Production volume of these four sites is 23,561 t/a of which 11,500 t/a is exported. The volume for the European market is thus 12,061 t/a. Production capacity was provided by three companies and it makes 43,200 t/a.

Table 1.1: Production sites of synthetic cryolite in the EU-15

Company	Location
Derivados del Fluor S.A.	Spain, Onton
Fluorsid S.p.A.	Italy, Assemini (Cagliari)
I.C.I.B. S.p.A.	Italy, Treviglio (BG)
Solvay Fluor und Derivate	Germany, Bad Wimpfen

By-production in aluminium smelters

Eleven aluminium smelters have provided information under Regulation 93/793/EEC. Four of these sites reported not to sell bath material on a regular basis or to use it completely for own purposes. One site reported to have imported cryolite. Total production volume of the eleven sites involved is 4,500 t/a (as cryolite). Of this amount, 700 t/a is sold to the EU market and 3,800 t/a exported. These volume estimates are based on the information from the years 1996-1998.

Table 1.2 presents the primary aluminium production sites located in European countries. Primary aluminium production in the year 2005 amounted to 3,101,000 t/a in the EU-27. The total aluminium production volume for the EU-15 and Norway was 3,758 kt/a in 2003 (EAA, 2006a).

The production rate of excess bath as cryolite is ca. 0.5-2 % w/w of aluminium produced. This range is derived from the estimates of three smelters which provided information under Regulation 93/793/EEC and agrees with the estimation approach presented in RAR-chapter 2.1.1. However, according to the information of industry, this rate may not apply to all sites as the process conditions vary largely from site to site. Multiplying the EU-15+NO volume of primary aluminium production (3,758 kt/a) by the production rate of excess bath formed gives a volume of 19,000 – 75,000 cryolite, which is considerably higher amount than the reported production volume from notified smelter sites (4,500 t/a). There may be several reasons for the difference in these volumes. EAA (2008a) has provided an estimate of 24,000 t/a cryolite in the excess bath material produced at the European aluminium smelter sites.

Uses

All sites producing cryolite intentionally and all aluminium smelters which provided information under Regulation 93/793/EEC provided information on uses and their shares of the volume sold.

The main volume of intentionally produced cryolite is used as bath material in aluminium smelters. Table 1.2 lists the primary aluminium production sites in Europe. Both synthetic cryolite and bath material from own by-production is used in the European smelters for the cryolite bath when new or relined aluminium pots are taken to use. The bath volume used for aluminium production can be increased, e.g., by the use of own excess cryolite. However, the volume is increased only if the aluminium production volume is increased. The volume of bath material in use in pots was reported only by six of the eleven smelter sites which notified under 93/793/EEC (9,350 t in total). The excess bath material is either stored for later use or sold to third parties for use in other aluminium smelters.

Cryolite is also used as filler in synthetic resins for abrasives and as binding agent for cutting or grinding discs. Closer information on the industrial categories for these uses is not available and hence the categories indicated in table 1.3 are assumed for the assessment.

Minor uses are the use as opacifier in glass and enamel industry, in pyrotechnics and in ceramic industry. According to the producers these uses make together ca. 13 % of the use volume. No further information was provided on these uses. These uses are covered in the assessment by the industrial category “others” (IC 15).

Cryolite is used in the United States as a plant protection product (insecticide) for i.a. vegetables and fruits (U.S.EPA, 1996). This use is not registered in the EU.

The SPIN (2006) database indicated for the four included Nordic countries that a volume of 2240.2 t in total in altogether 43 preparations were on the market in the year 2004 (Danish data from the year 2003). The most recent use data (Finland and Norway for the year 2004) indicate a use of 1853.3 t in the industrial category "manufacture/industry of basic metals" (83 % of total amount). The other industrial categories between the years 2001 and 2004 have been "industry for fabricated metal products, except machinery and equipment", "industry for other non-metallic mineral products" and "manufacture of chemicals and chemical products", whereas the use categories were "raw materials for production of metals", "others", "fillers" "process regulators" and "flux agents for casting". This information is in accordance with the data provided by industry.

Table 1.2: Primary aluminium production sites in Europe (EAA 2006b). Some of the sites were closing by 2006.

Company	Location(s)
Elkem Lista	Norway
Elkem Mosj.	Norway
Hydro Årdal	Norway
Hydro Høyan	Norway
Hydro Karm	Norway
Hydro Sund	Norway
Søral AS	Norway
Trimet Aluminium	Germany
[Hydro Stade]	[Germany]*
Hydro Neuss	Germany
HAW	Germany
Corus Voerde	Germany
Aluminium Delfzijl	Netherlands
PNL Vlissingen	Netherlands
Anglesey Al.	United Kingdom
Alcan Lynem	United Kingdom
Alcan Lochab	United Kingdom
Nordural	Iceland
Alcan Isal	Iceland
Kubikenborg AB	Sweden
Talum	Slovenia
Slovalco	Slovakia
Aluminium of Greece	Greece
[Alcan Lannemezan]	[France]*
Alcan Dunkirk	France
Alcan St. J. De Maurienne	France
Alcoa San Ciprian	Spain

Company	Location(s)
Alcoa Aviles	Spain
Alcoa La Coruna	Spain
Alcoa P. Vesme	Italy
Alcoa Fusina	Italy
[Alcan Steg]	[Switzerland]*

* Activity stopped according to EAA (2007b,c).

Table 1.3: Known uses of cryolite from intended production.

Industry category*	Use category*	Quantity used t/a	Percentage of total use
Aluminium smelters (primary and recycled; IC 8)	Flux agent (UC 24)	5,343	44.3
Engineering industry (IC 16)	Filler in synthetic resins for abrasives (UC 55/0)	3,750	31.1
Metal extraction, refining and processing industry (IC 8)	Binding agent in cutting or grinding discs (UC 2)	1,353	11.2
Pyrotechnic industry Glass industry Ceramics industry (IC 15/0 = others)	Colouring agent, opacifier (UC 10).	684	5.7
Metal extraction, refining and processing industry (IC 8)	Opacifier in enamel production (UC 10 assumed)	931	7.7
Total		12,061	100

* Descriptions of uses and IC/UC numbers provided by the notifiers are not consistent and partly lack information on volumes. The contents of the table is therefore an interpretation of the Rapporteur. Background information on the compilation of the table is confidential.

2 The Risk Assessment

2.1 Workers

Introductory remarks

Occupational exposure to cryolite may occur during production and further processing and use of the substance. This risk assessment is based upon the occupational exposure assessment (RAR-chapter 4.1.1.2) and the toxicological profile of cryolite (RAR-chapter 4.1.2). The threshold levels identified in the hazard assessment are taken forward to characterise the risks at the workplace and give indication for concern according to the MOS approach as outlined in the TGD (Human Health Risk Characterisation, Final Draft).

Systemic availability for different routes of exposure

For cryolite information on absorption mainly comes from fluoride determination (F^-) in excrements (animal or human studies) after oral application. Very little is known on the absorption and bioavailability of the aluminium-containing moiety. On the background of the fluoride data the oral absorption in humans is assumed to be 95 % based on the study of Largent and Heyroth (Largent and Heyroth, 1948). For animals, 85 % oral absorption is taken for risk characterisation in animals (rats) based on the study of Wright and Thompson (1978). Inhalation data are rare but give indication that also after inhalation of cryolite dust a considerable amount of F^- may be absorbed. For inhalation a default value of 100 % absorption is taken forward to worker risk assessment. For dermal absorption no data are available. A value of 10% for dermal absorption of cryolite is assumed, because cryolite is insoluble in organic solvents and thus will not easily pass the lipophilic stratum corneum of the skin. Furthermore, salts are usually poorly absorbed via the dermal route. In all cases it has to be recognised, that the information on absorption only applies to the F^- content of the cryolite molecule.

Occupational exposure and internal body burden

In table 2.1 the exposure levels of the RAR-table 4.1 which concern cryolite are summarised and the route-specific internal body burdens of F^- are identified. To this end the F^--content in cryolite of 54% is taken into account in combination with the route-specific percentages for absorption (100 % for inhalation and 10 % for dermal exposure). For combined exposure the internal body burdens of F^- by inhalation and dermal contact are summed up to give a total internal body burden.

Table 2.1: Occupational exposure levels (cryolite) and internal body burden (F^-)

Exposure scenario	Inhalation	Dermal contact		Internal body burden of F^- of workers after repeated exposure[1]		
	shift average	shift average		Inhalation[2]	Dermal[3]	Combined
	mg/m^3	mg/pers/day	mg/kg/day	mg/kg/day		
1. Production of synthetic cryolite dust	5	42	0.6	0.38	0.03	0.41
Production of synthetic cryolite granules	1	42	0.6	0.08	0.03	0.11
2. Aluminium industry	2	84	1.2	015	0.07	0.22
3. Use in other industries	10	3000	43	0.8	2.3	3.1
4. Abrasives, grinding discs EASE[4]	1	252	3.6	0.08	0.2	0.28
Abrasives, grinding discs analogous data[5]	0.1	252	3.6	0.008	0.2	0.208

(1) taking into accout the F^- content of cryolite of 54%
(2) based on the assumption of 100% inhalative absorption; breathing volume of 10 m^3 per shift
(3) based on the assumption of 10% systemic availability of fluoride after dermal contact
(4) without LEV
(5) with LEV

MOS Approach

The MOS approach for human risk characterisation is described in detail in the TGD (Human Health Risk Characterisation, Final Draft). The following paragraphs contain a short introduction to aspects relevant in case of cryolite. The basic principle of the MOS approach is a comparison of scenario-specific MOS values (the relationship between the experimental NOAEL respectively the adjusted starting point and the exposure level) with a reference MOS (product of various assessment factors).

MOS calculation and the adequate starting point

Basically, MOS values are calculated as quotient of a relevant NOAEL from experimental animal testing or human studies and actual workplace exposure levels. In specific situations, the MOS approach requires converting the original NOAEL into an adequate starting point or corrected NOAEL previously to MOS calculation in order to be directly comparable to the exposure assessment. If the route of application in animal or human studies is different from the actual occupational exposure, the dose units of the experimental data are converted to the dose unit of the exposure data. Additionally, possible differences in bioavailability between

routes, as well as possible differences in bioavailability between animals and humans are accounted for in the calculation of the corrected NOAEL. If necessary in occupational risk assessment, the starting point for inhalation risk assessment also includes a correction for the difference between the standard respiratory volume of a person at rest (6.7 m^3) and the respiratory volume of workers under light activity (10 m^3).

MOS values are calculated for different routes of exposure and for different toxicological endpoints. In occupational risk assessment inhalation and dermal contact generally resemble the relevant exposure routes. In addition, for assessment of combined risks the simultaneous exposure by inhalation and dermal contact needs to be considered. For cryolite the adequate NOAEL in this case is given by the respective internal level of fluoride which is expressed as well in mg F^-/person as in mg F^-/kg. This is easily comparable to the data on occupational and non-occupational fluoride uptake, which also are given as internal values (internal body burden). Inhalation exposure and dermal exposure to cryolite may contribute differently to the internal body burden of fluoride. With respect to the possible outcome of an assessment for combined risks, interest focuses on scenarios with conclusion ii at both exposure routes. Based on theoretical considerations, combined exposure will not increase the most critical route-specific risk component more than twice.

Reference MOS

The MOS values calculated have to be compared with a reference MOS. The reference MOS results an overall assessment factor from the multiplication of the different specific factors for a certain risk situation. The Technical Guidance Document emphasis the different aspects which are involved in these considerations, especially the extrapolation of experimental data to the human situation. For several aspects default assessment factors are recommended. It is important to point out that any relevant substance-specific data and information may overrule the defined default values.

Interspecies extrapolation as one central element is based on allometric scaling (factor 4 for rats, factor 7 for mice, and factor 2 for rabbits). For remaining interspecies differences the TGD proposes an additional factor of 2.5. Another element is adjustment for intraspecies differences. For workers, a default factor of 5 is recommended, based on an evaluation of empirical data by Schneider et al. (2004). It is anticipated that a default factor of 5 will be sufficient to protect the major part of the worker population (about 95%). For cryolite these default assessment factors are indicated for some endpoints only, because in most cases reliable human data are available which are preferred as direct basis for the assessment.

It is usually expected that the experimental NOAEL will decrease with increasing duration of application. Furthermore, other and more serious adverse effects may appear with prolonged exposure duration. This may result in the necessity to perform a duration adjustment of data using default factors. For cryolite however, data on health effects after chronic exposure are available which are sufficient for the assessment. There is no need for a numerical correction.

The TGD describes two further adjustment factors (uncertainty in route-to-route extrapolation and dose-response relationship including severity of effect) which in specific cases may be different from one. For cryolite there are uncertainties from route-to-route extrapolation and from dose-response relationship especially for the endpoint carcinogenicity. However, the problem is not dealt with additional assessment factors but reference is made to repeated dose toxicity and the respective risk characterisation.

Comparison of MOS and reference MOS

The different scenario- and endpoint-specific MOS values are compared with the respective reference MOS. MOS values clearly above the reference MOS do not lead to concern, whereas MOS values that are clearly below the reference MOS give reason for concern. There are also risk-related aspects which cannot be covered quantitatively by assessment factors. These additional aspects are considered qualitatively when performing the risk assessment and have adequate influence on the finding of the conclusions. Especially in case of borderline scenarios these aspects might be decisive.

Critical Exposure Levels

In a parallel procedure, which gives identical but more direct results, the adjusted toxicological starting point is directly divided by the reference MOS. As a result, an exposure level (in mg/m³ or mg/kg/d) is identified, which may serve as a direct trigger for decisions when compared with the occupational exposure levels. In the context of this risk assessment report this trigger value is called "critical exposure level". Concern will be expressed for scenarios with occupational exposure levels higher than the relevant "critical exposure level".

Acute toxicity

From acute inhalation studies in animals with cryolite dust there is indication for severe local effects in the respiratory tract, leading to mortality at high air concentrations. These effects have been evaluated in the RAR-chapter 4.1.3.2.3, irritation and corrosivity, in combination with the results of the short-term inhalation studies. These also give evidence of significant local irritation properties of cryolite and allow for a quantitative analysis. For the evaluation of acute toxicity in this chapter the local effects in the acute inhalation study therefore are not used.

From the oral and the dermal application route there is no indication for adverse systemic effects of cryolite after short-term exposure up to limit doses. In a guideline-compliant rat inhalation study, a LC50 of 4,470 mg/m^3 was derived. No mortality and no clinical sings were observed at 1,330 mg/m^3 . The highest occupational exposure value is described in scenario 3 with 10 mg/m^3. Compared to the value of 1,330 mg/m^3, where no severe effects are described, the margin of safety is judged to be sufficient. This is confirmed by data from workers with high exposure to cryolite and by the different long-term studies, which did not give evidence of acute symptoms except those of local irritation.

In summary there is no indication that significant systemic effects might be caused by short-term exposure to cryolite at the workplace, there is no concern for workers from this aspect.

Conclusion: ii

Irritation and corrosivity

Skin

There is no standard skin irritation test available. In a well-conducted skin sensitisation study (GPMT) no dermal reactions at all have been obtained. From literature data cryolite is said to be not irritating to skin. There are no reports on skin effects from the different studies on workers. In summary there is no concern for dermal irritation at the workplace.

Conclusion: ii

Eyes

Information on eye irritation indicates that cryolite may have a certain potential for eye irritation, but due to the low quality of the available data a final assessment is not possible. A precautionary classification with R36 is proposed.

Due to that insufficient data base for C&L decisions conclusion (i) on hold applies.

Conclusion: i (on hold)

Respiratory tract

From human examinations no local effects on the respiratory tract were described. Also in the rat LC_{50}-study no clinical signs of respiratory tract irritation were observed at 1,330 mg/m³. However, in animal studies with longer duration (14-day inhalation study with 5.1, 14, 60, 130, 470 mg/m^3 of particulate test substance) various inflammatory lesions were observed which concerned the alveolar parenchyma, the bronchiolar –alveolar junctions and the lumen of the large bronchioles slight bronchiolar hyperplasia. Also after chronic inhalation of Cryolite, rats showed lung changes.

With respect to short-term single exposure up to 10 mg/m³ (highest exposure value, resulting from scenario 3), severe airway damage is not anticipated and no concern is expressed. For the assessment of local effects after repeated contact see the chapter below.

Conclusion: ii

Sensitisation

Skin

In a fully guideline-compliant Magnusson Kligman Test a skin sensitising potential of cryolite could not be demonstrated. Also monitoring data at the workplace do not indicate specific skin reactions of workers to cryolite. There is no concern with respect to skin sensitisation of cryolite.

Conclusion: ii

Respiratory tract

No information on the sensitising potential of the substance at the respiratory tract is available. For the time being a valid study to investigate respiratory sensitisation in experimental animals cannot be recommended. Some cases of bronchial asthma have been observed at workplaces with mixed exposure to several chemicals, which however, did not give notice of a specific sensitising potential of cryolite. These effects are dealt with in the RAR-chapter 4.1.3.2.2, irritation and corrosivity, respiratory tract. On the background of these data cryolite is not suspected to be a potent respiratory sensitiser in humans. There is no concern with respect to respiratory sensitisation at the workplace.

Conclusion: ii

Repeated dose toxicity

Local effects

Inhalation exposure

For prolonged inhalation exposure of workers to cryolite, data on possible health effects are available from different sources such as mining and processing of natural cryolite, production of syntethic cryolite and manufacturing of aluminium. There has been no indication for cryolite specific chronic respiratory effects in humans although specific examinations have been made (x-ray photography, pulmonary function tests, questionaires concerning incidences of acute pulmonary symptoms). Exposure in some cases has been rather high and long-lasting, causing severe skeletal fluorosis.

In a well-conducted 90-day inhalation study rats were exposed snout-only to particulate aerosols of cryolite in the concentration of 0, 0.21, 1.04, and 4.6 mg/m^3. Alveolitis with interstitial thickening of alveolar duct walls and increased collagen in alveolar ducts occurred in the high dose group. At the intermediate dose of Cryolite, a proportion of rats had interstitial thickening of the alveolar duct walls. These effects might indicate of the start of a fibrotic process in the lung. At the low dose (0.21 mg/m^3) no effect was observed.

For the risk assessment this NOAEC of 0.21 mg/m^3 is used as starting point concerning effects of cryolite after repeated inhalation.

For the identification of the reference MOS the following aspects are taken into account: The human data give no indication for cryolite specific chronic respiratory effects. Therefore, the NOAEC gives a very precautious value for the evaluation of this endpoint. On that background it does not seem indicated to apply any additional assessment factors like inter- or intraspecies extrapolation or duration adjustment. On the other hand the NOAEC, based on a 90-day study, might make a duration factor of about 2 necessary, because a progression of effects in the lungs (thickening of alveolar ducts and increased collagen) cannot excluded. In summary for the reference MOS a value of about 2 is proposed; the critical exposure level calculates then to 0.1 mg/m^3 (0.2 mg/m^3 / 2).

Table 2.2 shows, that all scenarios exceed the critical exposure level thus giving reason for concern.

Conclusion: iii

Table 2.2 Irritation and Corrosivity, respiratory tract

	Inhalation		
Starting point for MOS calculation	0.2 mg/m^3		
Reference MOS	2		
Critical exposure level	0.1 mg/m^3		
	Exposure (mg/m^3)	MOS	Conclusion
1. Production of synthetic cryolite dust	5	0.04	iii
Production of synthetic cryolite granules	1	0.2	iii
2. Aluminium industry	2	01	iii
3. Use in other industries	10	0.02	iii
4. Abrasives, grinding discs EASE	1	0.2	iii
Abrasives, grinding discs analogous data	0.1	2	iii borderline

Dermal contact

No data are available concerning local effects after repeated dermal contact with cryolite. The acute skin tests did not show local irritating or sensitizing properties. From epidemiological data no observations on skin reactions from workers have been reported. In summary local effects by prolonged skin contact of workers are not expected. There is no reason for concern.

Conclusion: ii

Systemic effects

Repeated dose studies in mice and rats with oral and inhalation application demonstrated that prolonged exposure to cryolite causes accumulation of fluoride in teeth and bones with striations of the teeth and development of abnormally structured osseous tissues. From a well-conducted 90-day inhalation study in rats the systemic NOAEC is identified as 0.21 mg cryolite/m^3. With oral application fluoride accumulation in bone and teeth was observed in rats from the lowest dose tested upwards. The respective LOAEL is 50 ppm, corresponding to 3.8 mg cryolite/kg/day for male and 4.5 mg cryolite/kg/day for female rats. In a 5-month rat study a NOAEC for toxic effects on bones, teeth and for local effects on the respiratory tract

was established at 0.5 mg/m^3 (6h/d, 6d/week). At ≥1 mg/m^3 there were dystrophic lesions on the bones and teeth, and also adverse effects on the respiratory tract, stomach, kidney, liver, and brain.

From prolonged occupational inhalative exposure to cryolite dust it is known that cryolite may cause skeletal fluorosis in humans which is characterized by increased mineralisation of the bones and is identified in x-ray examinations by e.g. increased bone density, narrowing of the medullary cavity and ligament calcification. Joint pain and limited movement of the joints belong to the clinical symtoms. In severe cases skeletal crippling might occur with progressive disability. Also osteosclerosis can lead to brittle bones and a higher frequency of fractures. The underlying cause of the disease is the incorporation of fluoride into the bone tissue.

The human NOAEC for inhalation is derived in this report from a study in aluminium smelter workers with long-term occupational exposure and is given as 0.48 mg F^-/m^3 (see RAR-chapter 4.1.2.6.3.2 summary of human toxicity data). Taking into account an occupational respiratory volume of 10 m^3 in 8 hours and the fact that oral and inhalation absorption of cryolite are in a comparable range and relatively high (95% and 90% for oral and inhalation absorption, respectively), this value corresponds to an oral dose of about 5 mg F^- per person caused by cryolite. This may be compared to the evaluation of drinking-water data from China and India by the WHO (EHC 2002). The data give indication for an increased risk of effects on the skeleton at total fluoride intakes above about 6 mg F^-/person/day.

There is also concern with respect to dental fluorosis, which might occur as consequence of elevated fluoride levels in children under the age of 8 years (COT Statement 2003). Oriented to that, recommendation for intake of fluoride in the general population is given as 0.05 mg F^- /kg/day which is about two times below the level for skeletal fluorosis. However, for occupational risk assessment effects in children are not decisive.

The mechanism of cryolite toxicity in humans is comparable to that seen in animals. Quantitatively, however, animals appear to be more sensitive than humans. The inhalation NOAEC in rats is two times below the respective NOAEC in humans, if the NOAEC of 0.5 mg/m^3 from the 5-months rat study is used, not taking into account differences in exposure, assessment factors for species extrapolation or variability. Doing a MOS calculation the corresponding critical exposure level would result in a value of 0.02 mg/m^3 (0.5 / 25 with 2.5 for interspecies differences, 5 for intraspecies differences and 2 for duration adjustment) Oral data are difficult to compare because a NOAEL in animals has not been identified. Risk assessment at the workplace will be based on the F^- levels in humans which are identified as no effect levels with respect to skeletal fluorosis. From two completely different data sources two very similar values have been obtained (see above). It is recognised that the NOAEC from the animal data would lead to a more cautious assessment which, however, is not assumed to be representative for humans.

Inhalation exposure

Using directly the human NOAEC of 0.48 mg F^-/m^3 for workers as starting point for risk assessment and taking into account the F^- content of cryolite of 54 % reveals a critical air concentration for cryolite at the workplace of 0.89 mg cryolite/m^3 (0.48 mg F^- x 100/54 cryolite/ F^-). As alternative, risk assessment could be based on the reference value for fluoride of 6 mg F^-/person/day. Doing so, it should be taken into account that fluoride intake by food and drinking water in Europe is assumed to be about 1 mg F^-/person/day. Additional intake of fluoride by workplace conditions should therefore not exceed 5 mg F^- /person/day. Under this

presumption the critical air concentration of cryolite would be 1.03 mg cryolite/m^3 for workers inhaling 10 m^3 per shift and taking into account the F^- content of cryolite and assuming 90 % absorption by inhalation (5 mg F^- x 100/54 cryolite/F^- / 0.9 / 10 m^3).

The German MAK-value for fluoride has recently been set to 1 mg F^-/m^3 (DFG 2005). It is recognised that application to cryolite would reveal an air concentration of 1.9 mg cryolite/m^3 (1 mg F^- /m^3 x 100/54 cryolite/F^-).

The human NOAEC of fluoride for workers of 0.48 mg F^- which corresponds to about 0.89 mg cryolite/m^3, and the reference value for fluoride from the WHO which corresponds to about 1.03 mg cryolite/m^3 are quite similar. In this report for risk assessment at the workplace a value of 1 mg cryolite/m^3 is used as critical exposure level. Additional assessment factors for worker risk assessment are not deemed necessary. The reference MOS is 1. Borderline scenarios are included in the concern range taking into account that no specific precautionary elements have been included in inhalation risk assessment.

As can be seen from table 2.3 air concentrations of cryolite in the aluminium industry and during use in other industries clearly exceed the critical exposure level thus giving reason for concern. During production of synthetic cryolite exposure may occur against dust or granules, the latter one giving lower air concentrations. In both cases however there is reason for concern. The same holds true for grinding activities. By two methodical approaches a spectrum for the exposure data is given, which results at the upper end in a borderline scenario. These risks should not be neglected.

In summary concern is to be expressed for all scenarios (1 – 4). For grinding activities under certain conditions risks can be excluded.

Conclusion: iii

Dermal contact

No specific data are available to assess the systemic toxicity of cryolite after repeated dermal contact. For a first approximation also the maximum additional fluoride intake of 5 mg F^-/person or 0.07 mg F^-/kg is used as reference (see inhalation exposure). Taking into account the F^- content of cryolite and assuming 10 % skin absorption results in an exposure level for workers of 92 mg cryolite/person/day (5 mg F^- x 100/54 cryolite/F^- / 0.1) or 1.3 mg cryolite/kg/day as starting point for risk assessment. Since additional assessment factors for worker risk assessment are not deemed necessary this value similarly resembles the critical dermal exposure level. The reference MOS is 1.

According to table 2.3 for production of cryolite (scenario 1) and the use of cryolite in the aluminium industry (scenario 2) the dermal exposure is low enough to be out of the concern range. However with a MOS of 1.1 in scenario 2 it is still very close. For the other scenarios a MOS below 1 gives clear indication for concern. It should be kept in mind though, that the uncertainty of the assessment is high because for dermal absorption of the dusty material a value of 10 % is assumed without data. As way forward, robust information on dermal absorption of fluoride from solid cryolite could significantly improve the risk assessment.

Conclusion: iii

Combined exposure

For all exposure scenarios of cryolite, there is concern for one or both routes of exposure and thus for combined exposure as well. A special case is production of synthetic cryolite using granules because inhalation and dermal exposure are each associated with borderline results. In combination, however, this leads to clear indication of concern. For quantitative data see table 2.3.

Conclusion: iii

Table 2.3 Repeated dose toxicity, systemic effects

	Inhalation(1)			Dermal(1)			Combined(2)		
Starting point for MOS calculation	1 mg/m^3			1.3 mg cryolite/ kg/day			0.07 mg F^-/kg/day		
Reference MOS	1			1			1		
Critical exposure level	1 mg/m^3			1.3 mg/kg/day			0.07 mg F^-/kg/day		
	Exposure (mg/m^3)	MOS	Conclusion	Exposure (mg/person/d)	MOS	Conclusion	Internal body burden (mg/person/d)	MOS	Conclusion
1. Production of synthetic cryolite dust	5	0.2	iii	0.6	2.2	ii	0.38	0.2	iii(3)
Production of synthetic cryolite granules	1	1	border-line iii	0.6	2.2	ii	0.1	0.7	iii(3)
2. Aluminium industry	2	0.5	iii	1.2	1.1	ii	0.22	032	iii(3)
3. Use in other industries	10	0.1	iii	43	0.03	iii	3.0	0.02	iii(3)
4. Abrasives, grinding discs EASE	1	1	border-line iii	3.6	0.4	iii	0.27	0.26	iii(3)
Abrasives, grinding discs analogous data	0.1	10	ii	3.6	0.4	iii	0.207	0.3	iii(3)

(1) external exposure values for croylite are used for the assessment
(2) internal fluoride levels are used for the assessment
(3) conclusion iii already results from inhalative and/or dermal exposure

Mutagenicity

Cryolite does not induce gene mutations in a bacterial in vitro system. In vitro tests on induction of chromosomal aberrations (human lymphocytes) and unscheduled DNA synthesis (rat hepatocytes) are reported to be negative, but cannot be adequately assessed because of the lack of full reports. In vivo cryolite was negative in rat bone marrow chromosomal aberration tests after acute and repeated inhalation exposure.

In summary there is no reason for concern with respect to mutagenicity

Conclusion: ii

Carcinogenicity

In order that carcinogenicity studies with cryolite are not available and fluoride has been identified as the moity of toxicological concern, studies with fluorides other than cryolite are included for the risk assessment.

Four carcinogenicity studies with sodium fluoride (two diet studies and two drinking water studies, see RAR-chapter 4.1.2.8.1) are available. From these studies with NaF in rats and mice it was concluded that “the available data are sufficient to suggest that fluoride is not a carcinogenic substance in animals." (EU risk assessment of hydrogen fluoride).

Since the results with the oral studies with NaF give no indications that fluoride has a carcinogenic potential in animals, and taking into account that cryolite is not mutagenic there is no reason for concern for workers with regard to carcinogenicity of cryolite.

Conclusion: ii

Toxicity for reproduction

Effects on fertility

Cryolite was investigated for reproductive toxicity in a two-generation study in rats with dietary administration in the range of 15 to 150 mg/kg/day. Dental fluorosis as indication for fluoride accumulation occurred at all dose levels. The results of this study do not direct towards a specific potential of cryolite to cause adverse effect to fertility. During a study with repeated inhalation of cryolite in rats also organs of the reproductive system have been evaluated. No substance-related effects on these organs were observed up to an air concentration of 4.6 mg/m^3. Fluoride concentrations in bones and tooth samples, however, were increased at that dose.

In summary there is no indication for fertility risks caused by cryolite, a quantitative assessment is not deemed necessary, there is no concern for workers from this aspect.

Conclusion: ii

Developmental toxicity

Cryolite was investigted for prenatal developmental toxicity in rats, mice and rabbits with the oral route of administration. While from the studies with rats and with rabbits there was no prenatal developmental toxicity, some indications for bent ribs and bent limb bones were reported from the mice study. These anomalies were only reported at dose levels showing severe maternal toxicity. Thus the effects are not considered to be indicative for a substance specific teratogenic potential of cryolite. During the two-generation study with rats, administering 0, 14, 42, 128 mg cryolite/kg/day in the diet, growth retardation in postnatal development was observed. Because this effect ocurred without any significant sign for systemic toxicity it is considered indicative for a specific toxic potential of cryolite adverse to postnatal development. The respective NOAEL in the diet study was 42 mg cryolite/kg/day. This value is taken forward for risk assessment. Data for other routes or human data are not available.

Inhalation exposure

Inhalation risk assessment will be based on the oral NOAEL of 42 mg cryolite/kg/day from the two-generation rat study. Taken forward to workers (bodyweight 70 kg) and taking into account oral absorption of 85% for animals and 100% inhalation absorption this value corresponds to an air concentration at the workplace of 250 mg cryolite /m^3 (42 mg/kg/day x 70 kg x 0.85/1 / 10 m^3), assuming a respiratory volume of 10 m^3 for workers in 8 hours shift. The air concentration resembles the corrected NOAEC and gives the starting point for inhalation risk assessment.

The following adjustment factors are applied for the identification of the reference MOS: (1) the allometric scaling factor for the rat is 4; (2) a default factor of 2.5 accounts for additional interspecies differences; (3) for intraspecies differences (workers) the default factor is 5. This gives a reference MOS of 50 (4 x 2.5 x 5). An adjustment for study duration is not deemed necessary. The critical inhalation exposure level at the workplace is identified as 5 mg cryolite /m^3 (250/50).

As can be seen from table 2.4 there is one inhalation scenario at risk (scenario 3: use in other industries). It has to be kept in mind though, that under the aspect of systemic toxicity the critical air concentration for repeated inhalation of cryolite is 1 mg/m^3. If this would be kept, developmental risks would also be diminished.

Conclusion: iii

Dermal contact

Also dermal risk assessment is based on the NOAEL from the two-generation diet study in rats. Taking into account oral (85%) and dermal (10 %) absorption a value of 357 mg cryolite /kg/day (42 mg cryolite/kg/day x 0.85 / 0.1) is used as starting point for the dermal route.

The following adjustment factors are applied for the identification of the reference MOS: (1) the allometric scaling factor for the rat is 4; (2) a default factor of 2.5 accounts for additional interspecies differences; (3) for intraspecies differences (workers) the default factor is 5. This gives a reference MOS of 50 (4 x 2.5 x 5). An adjustment for study duration is not deemed necessary. The critical dermal exposure level at the workplace is identified as 7.1 mg cryolite/kg/day (357/50).

As can be seen from table 2.4 there is one dermal scenario at risk (scenario 3: use in other industries). It has to be kept in mind though, that under the aspect of systemic toxicity the critical exposure level for repeated dermal contact with cryolite is 1.3 mg/kg/day (92 mg/person/day / 70 kg/person). If this would be kept, developmental risks would also be diminished.

Conclusion: iii

Combined exposure

For risk assessment of combined exposure the internal level of fluoride corresponding to the oral NOAEL is calculated as 19.3 mg F^- /kg/day (42 mg cryolite/kg/day x 0.85 x 0.54), taking into account the oral absorption percentage and the fluoride content of cryolite. This is used as starting point for combined risk assessment.

Similar adjustment factors as above for dermal and inhalation exposure are applied giving a reference MOS of 50. The critical internal fluoride level results as 0.39 mg F^-/kg/day (19.3/50) with respect to developmental toxicity.

In comparison to inhalation and dermal risk assessment one additional scenario is identified to be of concern because of combined exposure at both routes. However, from repeated dose toxicity the reference dose for fluoride uptake at the workplace is derived as 0.07 mg F^-/kg/day or 5 mg F^-/person/day. If this would be kept, developmental risks would also be diminished.

Conclusion: iii

Table 2.4 Developmental toxicity, postnatal effects

	Inhalation[1]			Dermal[1]			Combined[2]		
Starting point for MOS calculation	250 mg cryolite/m^3			357 mg cryolite/kg/day (external value)			19.3 mg F^-/kg/day (internal value)		
Reference MOS	50			50			50		
Critical exposure level	5 mg cryolite/m^3			7.1 mg cryolite/kg/day			0.39 mg F^-/kg/day		
	Exposure (mg/m^3)	MOS	Conclusion	Exposure (mg/ kg /d)	MOS	Conclusion	Internal body burden (mg/kg/d)	MOS	Conclusion
1. Production of synthetic cryolite dust	5	50	ii	0.6	595	ii	0.38	51	ii
Production of synthetic cryolite granules	1	250	ii	0.6	595	ii	0.1	193	ii
2. Aluminium industry	2	125	ii	1.2	298	ii	0.22	88	ii
3. Use in other industries	10	25	iii	43	8.3	iii	3.0	6.4	iii[3]
4. Abrasives, grinding discs EASE	1	250	ii	3.6	99	ii	0.27	72	iii
Abrasives, grinding discs analogous data	0.1	2500	ii	3.6	111	ii	0.207	93	ii

(1) external exposure values for croylite are used for the assessment
(2) internal fluoride levels are used for the assessment
(3) conclusion iii already results from inhalative and/or dermal exposure

Summary of risk characterisation for workers

As result of occupational risk assessment for cryolite, concern is expressed and risk reduction measures have to be initiated. The most important adverse health effects for which protection is needed are local irritation in the airways induced by repeated exposure and fluorosis caused by increased systemic fluor levels as result of repeated exposure to cryolite. Table 2.5 summarizes the toxicological endpoints of concern. Besides the ones already mentioned there

is also some concern with respect to developmental toxicity. In this case the combination of inhalation and dermal exposure results in concern for one scenario which is not at risk in the route-specific assessments (see table 2.5). For acute toxicity, respiratory irritation, skin irritation, respiratory sensitisation, mutagenicity and fertility no concern is expressed. Due to insufficient data base for eye irritation conclusion i (on hold) is expressed.

Table 2.5 Endpoint-specific overall conclusions for the occupational risk assessment of cryolite

Toxicological endpoints		concern
Acute toxicity	inhalation	ii
	dermal	ii
	combined	ii
Irritation/ Corrosivity	dermal	ii
	eye	i (on hold)
	acute respiratory tract	ii
Sensitisation	skin	ii
	respiratory	ii
Repeated dose toxicity	local, inhalation	iii
	local, dermal	ii
	systemic, inhalation	iii
	systemic, dermal	iii
	systemic, combined	iii[(1)]
Mutagenicity		ii
Carcinogenicity	inhalation	ii
	dermal	ii
	combined	ii
Fertility impairment	inhalation	ii
	dermal	ii
	combined	ii
Developmental toxicity	inhalation	iii
	dermal	iii
	combined	iii

(1) conclusion iii already results from dermal exposure and/or inhalation, therefore no specific concern for the combined exposure scenario is indicated

Risk estimation is based either upon epidemiological studies of certain working populations exposed to cryolite or on long-term inhalation studies with cryolite dust (rats). For oral absorption of fluoride a value of 95 % is used and for the inhalation route 90% is taken, both on the background of experimental data. For dermal absorption a value of 10% is assumed to be reasonable, however, reliable data are not available.

Tables 2.6 (inhalation) and 2.7 (dermal contact) intend to visualize the risk profile of cryolite. According to the arrangement of the tables high risks occur on the left side, low risks on the right side of the table-matrix.

With respect to local effects in the airways after repeated inhalation exposure levels to cryolite dust should be controlled to values in the range of 0.1 mg/m^3 (critical exposure level for local effects after repeated exposure). In doing so, inhalation risks from other endpoints, especially adverse effects by fluorosis after long-term exposure (critical exposure level: 1 mg/m^3), as well as risks by developmental toxicity (critical exposure level: 6.2 mg/m^3) are similarly and effectively be mitigated too.

Special attention should be given to skin contact. From the risk assessment there is indication that repeated dermal exposure at the workplace to cryolite dust might contribute to critical elevated systemic fluoride levels. This could lead to fluorosis and also an elevated cancer risk cannot fully be ruled out. If it causes severe problems to controll the dermal exposure situation at the workplace to a level below 1.3 mg/kg/day or 92 mg/person/day (critical exposure level for fluorosis), a suitable dermal absorption study could give an additional option to refine the dermal risk estimation and might be taken into consideration.

To prevent adverse health effects by fluorosis according to the WHO (EHC 2002) a total daily uptake of 6 mg F^-/person should not be exceeded. In this respect cryolite exposure at the workplace is only one factor among others which might contribute to systemic fluoride accumulation. To control the different sources for elevated systemic fluoride levels a more general approach is needed which includes fluoride uptake by working conditions as well as fluoride exposure of the general public by other sources too. This however is no subject of this report.

Table 2.6: Ranking of health risks for workers (inhalation)

Exposure scenario	Exposure level in mg/m³	Repeated dose toxicity, local effects	Repeated dose toxicity, systemic effects: fluorosis	Developmental effects
		Critical exposure level in mg/m^3		
		0.1	1	5
3. Use in other industries	10	iii	iii	iii
1. Production of synthetic cryolite dust	5	iii	iii	
2. Aluminium industry	2	iii	iii	
1. Production of synthetic cryolite granules	1	iii	borderline iii	
4. Abrasives, grinding discs EASE	1	iii	borderline iii	
Abrasives, grinding discs analogous data	0.1	borderline iii		

(1) blank fields: conclusion ii

Table 2.7: Ranking of health risks for workers (dermal contact)[(1)]

Exposure scenario	Exposure level in mg/kg/day	Repeated dose toxicity, systemic effects: fluorosis,	Developmental toxicity
		Critical exposure level in mg/kg/day	
		1.3	7.1
3. Use in other industries	43	iii	iii
4. Abrasives, grinding discs EASE, analogous data	3.6	iii	ii
2. Aluminium industry	1.2	ii	ii
1. Production of synthetic cryolite dust, granules	0.6	ii	ii

(1)

2.2 Consumers

Exposure of consumers to cryolite occurs via inhalation through use of glazes in pottery. For the use of powdery cryolite the modelled data by EASE estimation without local exhaust ventilation was selected with considering a duration of 1 hour an inhalation exposure of 6.25 mg/m^3.

The bioavailibility is estimated as 100 % after inhalation.

Acute toxicity

Human data on the acute toxicity of cryolite are not available.

Inhalation

In a well conducted and guideline-compliant rat inhalation study, a LC50 of 4470 mg/m3 was derived. Therefore, a classification as harmful and labelling with R20 is appropriate. Taken into account the exposure value of 6.25 mg/m3 derived from a worst case scenario the margin of safety is judged to be sufficient.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Irritation and corrosivity

Skin

Standard skin irritation tests on cryolite are not available. The reported consumer exposure sources did not covered dermal scenarios. Therefore there is no concern for consumers.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Eye

Information on eye irritation indicates that cryolite may have a certain potential for eye irritation. Due to insufficient data quality a final assessment is not possible. Since eye protection measures of consumers does not exist there is concern for eye effects. Due to that insufficient data base for C&L decisions conclusion (i) on hold applies.

Conclusion (i) on hold There is a need for further information and/or testing.

Respiratory tract

Chronic as well acute toxicity studies showed that there are no severe effects regarding respiratory irritation mediated by cryolite. Human data are lacking. Therefore classifcation and labelling is not necessary that leads to no concern for consumers.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Sensitisation

Skin

A skin sensitisation potential of cryolite could not be demonstrated in a fully guideline-compliant Magnusson Kligman Test. Therefore there is no concern for consumers regarding skin sensitisation.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Respiratory tract

Regarding the sensitising potential of cryolite at the respiratory tract no information is available. Therefore there is no concern for consumers regarding respiratory sensitisation.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Repeated dose toxicity

Since the relevant consumer exposure scenarios are characterized by inhalation of cryolite dermal and oral repeated dose toxicity was not further calculated.

Inhalation

The human NOAEC for inhalation is derived from a study in aluminium smelter with long-term occupational exposure and is given as 0.48 mg fluoride/m^3 for skeletal fluorosis. Animal data showed dystrophic lesions in bones and teeth and adverse effects in the respiratory tract, stomach, kidney, liver and brain in a 5-month inhalation study in male and female rats with a systemic NOAEC of 0.5 mg/m^3 that should be used for risk characterisation.

For the decision on the appropriateness of MOS, the following aspects have been considered and taken into account

-overall confidence in the data base:

The data taken into account for performing the risk characterisation have been evaluated with regard to their reliability, relvance and completeness according to section 3.2 of the TGD

-uncertainty arising from the variability in the experimental data:

The data on toxicity after inhalation exposure is sufficient to allow the identification of an effect level for risk characterisation. There are no reason to assume a special extent of uncertainty which has to be taken into account.

intra- and interspecies variation:

Available data do not allow a conclusion on the intraspecies or interspecies variability of the toxicokinetic or toxicodynamic characteristics of cryolite under consideration.

The nature and severity of the effect:

The observed adverse effects in animals and humans are regard as serious. The systemic health effects are the basis for the classification as toxic, R48/23/25.

- dose-response relationship:

There is no reason to assume a special concern

The human population to which the information on exposure applies: following the exposure pattern there is no reason to assume a special risk for children, elderly, or pregnant women

-other factors:

There are no other factors known that might require a particular margin of safety.

MOS for the inhalation exposure scenario,systemic effects

Repeated exposure by inhalation of cryolite for 90 days caused lung lesions in male and female rats. After chronic inhalation of cryolite for up to 5 months dystrophic lesions in the bones and teeth, and adverse effects in the respiratory tract, stomach, kidney, liver, and brain were noted in both male and female rats. The NOAEC for systemic effects was set at 0.5 mg/^{3} of cryolite and selected for risk characterisation.

The margin of safety between

exposure level of 6.25 mg/m^3

and the

inhalative NOAEC of 0.5 mg/m^3

is judged to be not sufficient.

MOS calculation for local effects is not necessary since uncertainties exist whether the lung lesions detected in animal studies are relevant for humans.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Mutagenicity

Cryolite was tested in a bacterial in vitro system and in mammalian cellular in vitro systems with negative results. In in vivo rat bone marrow chromocomal aberration tests cryolite showed negative test results after acute and repeated inhalation exposure. Therefore there is no concern for consumers.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Carcinogenicity

Data on the carcinogenic potential of cryolite from human experience and animal studies are available. There are limited data from humans that indicate a carcinogenic risk from exposure to cryolite. The excess cancer risk identified in workers exposed to fluorides, including fluoride-spar and aluminium production workers, may be due to other factors than fluoride exposure. In summary, it is difficult to relate the excess cancer incidence directly to fluorides. The available data in experimental animals are insufficient to demonstrate a carcinogenic effect of cryolite. Studies in dogs, rats and mice had been performed with synthetic cryolite

and the analog sodium fluoride (NTP studies). Due to negative and equivocal test results with synthetic cryolite and sodium fluoride there is no concern for carcinogenicity. The RAR on HF concluded that fluoride is not a carcinogenic substance.Therefore the handling of cryolite regarding carcinogenicity is safe for consumers.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Toxicity for reproduction

Effects on fertility

There is no indication for fertility risks caused by cryolite, therefore there is no concern for consumers. A quantitative risk characterisation is not necessary.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Developmental toxicity

Cryolite was investigated for prenatal developmental toxicity in rats, mice and rabbits with the oral route of administration. During the two-generation study with rats, administering 0, 14, 42, 128 mg cryolite/kg bw/day in the diet, growth retardation in postnatal development was observed. Because this effect occured without any significant sign for systemic toxicity it is considered indicative for a specific toxic potential of cryolite adverse to postnatal development. The respective NOAEL in the diet study was 42 mg cryolite/kg bw/day. This value is taken for risk characterisation and used for MOS calculation.

For the decision on the appropriateness of MOS, the following aspects have been considered and taken into account.

-overall confidence in the database:

The data taken into account for performing the risk characterisation have been evaluated with regard to their reliability, relevance and completeness according to section 3.2 of the TGD. Most of the animal data are citations from the secondary literature. The orginal data are not available. Due to the developmental effects described the proposal to classify cryolite as Repr. Cat 3, R63 is justified.

-uncertainty arising from the variability in the experimental data:

There are no reasons to assume a special extent of uncertainty

-intra- and interspecies variation:

Available data do not allow a conclusion on the intraspecies or interspecies variability of the toxicokinetic or toxicodynamic characteristics of cryolite under consideration.

The nature and severity of the effect:

The observed adverse effects in animals are regard as serious. The systemic health effects are the basis for the proposal of classification as repr. Cat. 3, R63.

- dose-response relationship:

There is no reason to assume a special concern

The human population to which the information on exposure applies:

following the exposure pattern there is no reason to assume a special risk for children, elderly, or pregnant women

-other factors:

There are no other factors known that might require a particular margin of safety.

MOS for the inhalation exposure scenario, local effects

Inhalation risk assessment will be based on the oral NOAEL of 42 mg cryolite/kg bw/day from the two-generation rat study. Taken forward to consumers (bodyweight 70 kg) and taking into acount oral (95%) and inhalation (90%) absorption this value corresponds to an air concentration for consumers of 3736 mg/m^3 (42 mg/kg bw/day x 0.95/0.9/0.83 m^3), assuming a respiratory volume of 0.83 for consumers in 1 hour shift. The air concentration resembles the corrected NOAEC.

The margin of safety between the

exposure level of 6.25 mg/m^3

and the

inhalative NOAEC of 3736 mg/m^3

is judged to be sufficient.

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Summary of risk characterisation for consumers

Concern is expressed and risk reduction measures should be intiated for consumer use in pottery. Inhalative repeated dose treatment of cryolite can induced fluorosis at relatively low doses. Regarding acute toxicity, skin irritation , sensitisation, mutagenicity, carcinogenicity and reproductive toxcicty no concern is expressed. Due to insufficient data base for eye irritation conclusion (i) on hold is appropriate.

3 Current Risk Reduction Measures

Classification and labelling

Classification of trisodium hexafluoroaluminate (Cryolite) according to Annex I of Directive 67/548/EEC (24th ATP (98/73/EC), Index number: 009-016-00-2):

T; R48/23/25 – Xn; R20/22 – N; R51-53.

Trisodium hexafluoroaluminate (Cryolite) has to be labelled with

T,N; R20/22-48/23/25-51/53; S(1/2-)22-37-45-61.

The following proposal for a harmonised classification and labelling was laid down in an Annex XV –Dossier:

Proposed classification based on Directive 67/548/EEC:

T; R48/23/25 – Xn; R20 – Xi; R36 - Repr.Cat.3; R63.

Abbreviations:

T	Toxic
Xi	Irritating
Xn	Harmful
N	Dangerous for the environment
Repr. Cat. 3	Toxic for reproduction-Category 3
R20	Harmful by inhalation
R20/22	Harmful by inhalation and if swallowed
R48/23/25	Toxic: Danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R36	Irritating to eyes
R51-53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R63	Possible risks of harms to the unborn child
S(1/2-)	Keep locked up and out of the reach of children
S22	Do not breathe dust
S37	Wear suitable gloves
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S61	Avoid release to the environment. Refer to special instructions/Safety data sheets

3.1 Workers

As a result of its classification as a hazardous substance trisodium hexafluoroaluminate (Cryolite) is subject to general regulations concerning its supply and handling.

Safety data sheets

In accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the council of 18 December 2006, corrected in May 07 and amended in November 07 (Regulation (EG) Nr. 1354/2007) anyone placing trisodium hexafluoroaluminate (Cryolite) on the market has to provide a safety data sheet to the professional user.

The information system for hazardous substances and preparations in the form of labelling and the safety data sheets is considered sufficient in principle to provide the user with appropriate information for the selection of suitable occupational safety measures.

Occupational safety and health regulations

Regarding the production and use of trisodium hexafluoroaluminate (Cryolite) the following directives are primarily applicable as general regulations for occupational safety and health at the European level:

- 98/24/EC on the protection of workers from the risks related to exposure to chemical agents at work
- 89/656/EEC on the use of personal protective equipment

Only limited knowledge is available about the extent to which the EU Member States have in each case transposed these basic requirements into national law.

Occupational exposure Limits

Industrial activities producing and using cryolite present opportunities for occupational exposure. Several Member States and the Commission have established occupational limit values.

Cryolith is regulated as a member of various chemical groups, for example “Fluorides, inorganic”, “Aluminum (soluble salts)” and “Fluorides, as F”.

The following occupational exposure limits (OEL (8-hour TWA)) and short term exposure levels (STEL) apply for these groups in the EU (Ariel WebInsight 5.1, 2008):

Country	OEL (mg/m^3)	STEL (mg/m^3)	Chemical group
Iceland	0,6		Fluorides, other than those on the list, as F
Norway	0,6		Fluorides, as F
Germany	1*	Short term (15 min) multiplication factor: 4	Fluorides, as F (inhalable fraction)
Denmark, Sweden	1		Aluminum (soluble salts)
Switzerland	1	4 Freq. x Duration in minutes/shift: 4x15	Fluorides (as F), inhalable dust
Belium, Finland, France, Greece, Iceland, Ireland, Netherlands, Norway, Portugal, Spain, Switzerland, UK	2		Aluminum (soluble salts)
Sweden	2		Fluorides, as F
Austria	2,5	12,5 Frequency x Duration in minutes:2x30	Fluorides, as F
Greece, Italy	2,5		Fluorides, as F
Belium, Denmark, Finland, Luxembourg, UK	2,5		Inorganic Fluorides (as F)
Netherlands		2	Inorganic Fluorides (as F)
EU (Directive 2000/39/EC)**, France, Ireland, Portugal	2,5		Fluorides, inorganic

* If the OEL value is complied with, there should be no risk of reproductive damage

** Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, OJ (L 142) 47, 16 June 2000.

Personal Protection Equipment (PPE) against dermal and eye exposure

According to community legislation workers have to be provided with suitable PPE if their health is at risk due to exposure against chemicals. PPE that protects against the risks of trisodium hexafluoroaluminate (Cryolite) is available. The type of filter and the material of gloves, material thickness and breakthrough time have to be specified in the Safety Data Sheet.

Are existing controls sufficient to limit occupational risks?

It has been concluded from the risk assessment that there is a need for limiting the risks due to repeated dose toxicity (local and systemic effects), and developmental toxicity. Local effects upon repeated doses in the airways were the most critical effect with a criticaleffect level (CEL) of 0.1 mg/m^3.In controlling this risk, also inhalation risks from other endpoints, especially systemic effects by fluorosis as result of repeated exposure and developmental toxicity would be effectively mitigated.

Special attention should be given to skin contact. The most critical effect again is repeated doses systemic toxicity (fluorosis). The critical exposure level is 92 mg/person/day (1.3 mg/kg/day). It was calculated assuming that 10% of cryolite is absorbed through the skin. As considerable (but still practical) effort has to be taken within the framework of workeplace legislation, in order to achieve this level of dermal exposure, dermal risk estimation might be refined by an additional suitable dermal absorption study.

3.2 Consumers

Cryolite is not currently regulated under Council Directive 76/769/EEC (Restrictions on the marketing and use of dangerous substances). Further literature searches did not select any regulation on community or national level.

4 Possible Further Risk Reduction Measures

4.1 Workers

The following further Risk Reduction Measure are considered to be probably effective :

- Occupational Exposure Limit
- Technical and organisational measures, specific training, and occupational hygiene on company level in the framework of Directive 98/24

The options are assessed in section 5.

4.2 Consumers

The following Risk Reduction Measures are considered to be probably effective or less effective.

For eye irritation

A classification and labelling Annex XV dossier is available in the registry of intentions under REACH regulation (http://echa.europa.eu). The finalisation of this process with the inclusion of the proposed C&L in the Directive 67/548/EEC or GHS is effectve for consumers.

For systemic adverse repeated dose effects marketing and use restriction is not possible in the ESR program anymore. Therefore only national regulation are effective to protect consumers for adverse effects.

5 Assessment of Possible Further Risk Reduction Measures

The TGD requires that possible further risk reduction options be examined against the following criteria

- effectiveness
- practicality
- economic impact
- monitorability.

5.1 Workers

Occupational Exposure Limit

Exposure reduction by technical and organisational measures and personal protection are accepted strategies in workplace legislation.In order to put these instruments into action on company level and to make them enforceable in the framework of worker protection legislation it is recommended to establish an occupational exposure limit for the primary alkyl amines assessed in this strategy.

The OEL should take into account the risk assessment (critical exposure level CEL 0. 1 mg/m^3 for the most critical effect). The OEL will also trigger that personal protective equipment is provided if workplace concentrations exceed the OEL.

Within the framework of workplace legislation an occupational exposure limit is an enforceable and effective means to make exposure control obligatory. If this OEL takes into account the risk assessment, it can also be considered to be an effective means for health protection in the workplace. It can be monitored by existing techniques of workplace measurement. The reduction of inhalative exposure is considered practical for the scenarios assessed in the RAR:

Scenario 1: Production of synthetic cyrolite

Measured exposures and model-data tend to be higher by a factor of 10 than the CEL for the most critical effect. However, the information which was available for risk assessment does not seem to reflect state-of-the-art technology in cryolite production. Measured data are too few to be representative and more than 10 years old. Only about 20 measurements were availabele. They were provided by 3 different producers and dated from 1994, 1996 and 1997. Therefore concern was derived from the upper end of EASE estimations. For powdery cryolite (dust, dry manipulation, LEV) exposures were estimated to 2 - 5 mg/m^3, for dust-suppressed (granular) cryolite to 0 - 1 mg/m^3.

The EASE-model is known to be conservtive. During the production of cryolite, exposure to dust in the area of bagging of powder in sacks or big-bags is regarded to be the main source of exposure. For the large-scale chemical industry high standards of control at the workplace are assumed to be practical even if the containment is breached, e.g. during filling, cleaning, maintenance, repair works and taking of samples. So it seems practical that a protective OEL can be complied with in the production of synthetic crylite.

Scenario 2: Use of cryolite in the aluminium industry

For assessing inhalation exposure levels and deriving concern measurements for anode changing (9.5 mg/m3 dust (geometric mean)) were taken. With cryolite beeing a fraction of 21 % and taking all information into account, 2 mg/m3 cryolite was regarded to represent the reasonable worst case for cryolite in workplace air in the aluminium industry.

This value is significantly higher than the envisaged OEL. Still, it is supposed that within the aluminium industry it is practical to comply with an OEL in the order of magnitude of 0,1 mg/m^3, at least as long as routine processes are concerned. Measured data provided for the RAR seem not specific enough to describe the state-of-the-art of different tasks and at different sites for the production of aluminium. Neither seem the default values derived from the EASE model to fully reflect exposures in the aluminium industry. .

For the production of aluminium, cryolite is part of a smelter bath contained in "pots" (electrolyses furnaces). Workers in aluminium smelters handle cryolite only for rare occasions of charging extra cryolite on the pots. Releases from the pot to room air are caused when the hoods are removed for renewal of anodes, for relining the pot, for tapping aluminium or excess cryolite and for adding bath constituents to the bath. The acute risks resulting from possible release of HF during the aluminium smelter are vital and higher than those from cryolite. Old pots and used anodes are taken out of service after 5 to 7 years of operation.

In 2003 the Norway project "Survey of occupational exposure of importance in developing occupational asthma by production of primary aluminium "stated that the main contribution to the occupational exposure in this industry is caused by episodes, typically short timed and with high concentrations, (Skaugset, 2008). Taking into account the high acute risks associated with the hydrofluoric acid which is present in the smelter process, it can be assumed, that on company level technical and organisational measures are taken to rigorously control exposures during every stage of the production process. It may be assumed, that the control of cryolite to a very low and safe level is practical and will not cause any extra measures or costs.

Scenario 3: Use of cryolite in other industries (e.g. production of abrasives, glass-ceramic industry, foundries)

The exposure to cryolite mainly takes place when solid cryolite is handled for inclusion into a matrix (critical tasks: weighing, dosing, charging or mixing). The use of grinding discs or abrasives containing cryolite is assessed separately in scenario 4.

Measured data and exposures assessed with the EASE model are in the same order of magnitude. For Risk Assessment the reasonable worst-case values were taken forward (10 mg/m^3) which are significantly higher than an envisaged OEL.

For assessing the practicality of an OEL it has to be taken into account, that the typical values which are achievable under the conditions of good practice will be significantly lower than worst case exposures.

- A study (Marquart 1999) showed, that for dumping of a variety of powders into mixers exposure levels of inhalable dust of 1,9mg/m^3 (1.9 to 27.6 mg/m^3) and full-shift exposures of 0,8mg/m^3 (0.8 to 12.1 mg/m^3) can be achieved. The study was performed in in

different formulating facilities with LEV and from packages of different size (mostly 25 kg bags,opened with a knife) were dumped into the mixers.

- Data from "Berufgenossenschaftlichen Meßsystem Gefahrstoffe" (BGMG) from different workplaces in the ceramic and glass industry show as 95% percentile (reasonable worst case) inhalable dust concentration of 7 mg/m^3 (324 personal measurements, 8-h TWA's, 1996-1999). In the production of abrasives (compounding, pressing plant, finishing) inhalable dust concentrations were 4.5 mg/m^3 (95 % values, 42 measurements, 8-h TWA's, 1996-1998) (Barig, 1999). Typical or good practice exposures tend to be significantly lower (factor 2-20) than 95% percentiles.

- EASE estimation is known to be a conservative model. Exposures of 5 - 50 mg/m^3 are calculated for dust, dry manipulation, without LEV, non-aggregating-dust Considering a duration of 1 hour an inhalation exposure of 0.63 – 6.25 mg/m^3 would results. According to convention this would be reduced to of 0.063 –0,625 mg/m^3 if it LEV was supposed to be present.

Even if it is assumed, that good practice will significantly reduce worst-case exposures, to use of cryolite in other industries seems to require a careful regime company level to avoid dust production on. Compliance with an OEL of about 0,1mg/m^3 seems only practical if, within the framework of worker protection legislation, employers chose from a variety of appropriate measures. The STOP-principle shall be followed, with closed provisions of dosing as the prefered approach. Using granular cryolite is also a measure to control exposures effectively. Organisational measures (reducing exposure time), hygiencic measures (washing after exposure) and training to work cleanly should be applied in addition to techical measures.

On the basis of the exposure information provided it is not possible to further assess the scenario – especially it is not possible to propose in detail the operational conditions which will reduce exposure to a level of 0.1 mg/m^3 neither is it possible to assess the economic impact on company level. It has however to be stressed, that workplace legislation provides significant flexibility to chose measures that are appropriate and feasible on company level.

Scenario 4: Use of abrasives and grinding discs (containing cryolite)

Borderline concern was derived in the Risk Assessment. The assessment was based on EASE-estimation with the additional assumptions that cryolite-content in grinding discs and abrasives is 20% and that only 10% of the dust generated in grinding operations is from the grinding tools. Worst-case exposures towards cryolite of 0.1mg/m3 (8 h TWA) with local exhaust ventilation and 1.0mg/m3 without LEV were calculated. For risk assessment the presence of LEV was supposed and a value of 0.1 mg/m3 cryolite was taken forward to represent a reasonable worst case situation.

Measured data for grinding operations show, that for short time and under unfavourable conditions higher inhalation exposure values are possible. Under such conditions however, OELs for the other components of grinding dust will be significantly exceeded (e.g. the German hygiene value for inert dust of 10 mg/m3). Therefore compliance with an envisaged OEL of 0,1 mg/m^3 for cryolite can be regarded as practical and according to state-of -the-art.

Technical and organisational measures, specific training, and occupational hygiene on company level in the framework of Directive 98/24

The risk assessment has resulted in concern because of dermal exposure in scenario 3 and 4. The risks from dermal exposure cannot be reduced by establishing and complying with an OEL. Dermal exposure can in principle be reduced by technical measures (e.g.closing systems) and organisational measures that reduce the frequency, duration and area of exposure, by training to work cleanly, by personal hygiene and by appropriate use of PPE. Training, information and hygienic measures are foreseen in the framework of workplace legislation.

Organisational measures and training are practical and of low or moderate economic impact. Documentation on company level makes them monitorable, but enforcement is on behalf of the Member States. The proof of efficiency of measures to control dermal exposure is generally difficult.

Taking into account, that the exposures that were taken forward for risk assessment were worst case values, it seems appropriate and sufficient, to apply the full range of technical and organisational measures foreseen in the framework of workplace legislation, with special attention to training, organisational measures and occupational hygiene.

Scenario 3: Use of cryolite in other industries (e.g. production of abrasives, glass-ceramic industry, foundries)

For deriving concern a field study of manual dumping of a relatively dusty powder was taken. (Lansink et al., 1996). Bags were cut open using a knife and the powder was allowed to flow into the mixer. Local exhaust ventilation was generally present. Exposure is due to direct contact with the flow of powder, deposition of the dust and contact with contaminated surfaces and the outside of the bags. The 90^{th} percentile of the data is used as the basis for the reasonable worst case (RWC) value. The exposure was determined as 1.9mg/cm^2 and a total exposure of 3000 mg/person/day (43 mg/kg/day), which is well above the critical exposue of 1.3 mg/kg/day.

Dermal exposure was assessed for the unprotected worker, so the use of gloves would reduce exposure sgnificantly (840 cm^2 (hands) x 1.9mg/cm^2 x 90%= 1436 mg/person /day) ,but it would still be about 1500mg/person /day or 20mg/kg/day.

For scenario 3 a careful regime to avoid dust production is already required in for reducing inhalative exposure to a level that is compliant with the envisaged OEL. Such a regime is considered to be practical to reduce exposure by a factor of 10 or more in the framework of worker protection legislation and would so be effective for the reduction of dermal exposure. On company level employers shall chose from a variety of appropriate measures within the framework of worker protection legislation. The STOP-principle shall be followed, with closed provisions of dosung as the prefered approach. Using granular cryolite is also a measure to control exposures effectively. Organisational measures (reducing exposure time), hygiencic measures (washing after exposure) and training to work cleanly should be applied in addition to techical measures.

Scenario 4: Use of abrasives and grinding discs (containing cryolite)

Dermal exposure was assessed with the EASE-model, starting with the calculation of total grindung dust (unprotected worker, wide dispersive use, direct handling, extensive, exposed area of 840 cm^2 (hands)). The model results in a level of exposure to total dust of 5 – 15 mg/cm^2/day, leading to 4200 – 12600 mg/person/day (60- 180 mg/kg/day). Taking into account that the content of cryolite in abrasive dust is only 2% and taking forward the higher end of the exposure–range, workers are assumed to be exposed to 252 mg/person/day of cryolite (3,6 mg/kg/day).

The assessment was made for the unprotected worker and the use of gloves would be an effective and practical measure to reduce – according to assessment conventions – exposure to 0,36 mg/kg/day, which is clearly below the lowest critical exposure level of 1,3 mg/kg/day.

Cryolite is only 2% of the total dust. When using gloves workers would still be exposed to 420 – 1260 mg/person /day of total dust. Depending on the nature of the grinding dust this might be too high, but improving occupational hygiene of grinding and abrasive processes is beyond the scope of this risk assessment.

5.2 Consumers

For the dust scenario in the intensive use of cryolite in the pottery by consumers the information on possible eye irritation effects is useful. Therefore the C&L finalisation process under the REACH regulation is important.

Information is needed for the possibility of systemic adverse repeated dose effects in the dust scenario. That information can only be provided at the national level, since marketing and use restriction is not possible in the ESR program anymore. Since cryolite is not mutagenic, carcinogenic and reprotoxic there seems to be no available driver for a negative CMR substance to protect consumers under the REACH regulation in an effective way if other adverse effects are covered.

6 Further Risk Reduction Measures Recommended

6.1 Workers

The risk reduction strategy recommends the following measures:

- to establish at Community level occupational exposure limit values for cryolite according to Directive 98/24/EEC
- information on the need of technical and organisational measures, specific training, and occupational hygiene on company level in the framework of Directive 98/24 in order to reduce dermal exposure in scenario 1, 3 and 4.

6.2 Consumers

The risk reduction strategy recommends the following measure:

To establish proposed C&L for eye protection

7 Marketing And Use Restrictions

Not applicable to cryolite .

8 Possible Monitoring Arrangements

9 Organisations consulted

Literature:

Lansink et al., 1996: C.J.M., Lansink, M.S.C., Beelen, J., Marquart, J.J., Van Hemmen; ”Skin exposure to calcium carbonate in the paint industry. Preliminary modelling of skin exposure levels to powders based on field data. TNO Report V96.064”, TNO Nutrition and Food Research Institute, Zeist (The Netherlands), 1996

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