A REVIEW OF THE TOXIC AND ASPHYXIATING HAZARDS OF CLEAN AGENT REPLACEMENTS FOR HALON 1301

A REPORT
BY THE
HALON ALTERNATIVES GROUP

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1. INTRODUCTION

This report has been produced by the New Extinguishants Advisory Group (NEAG), a sub-group of the United Kingdom Halon Alternatives Group (HAG). It contains a review of the toxic and asphyxiating hazards of clean agent fire extinguishants developed for use in fixed total flooding systems as replacements for halon 1301. The agents reviewed were CEA 410, FE13, FM200, INERGEN, ARGONITE and ARGOTEC.

Guidance on the toxic and asphyxiating hazards of halon 1301 and the safe operation of halon 1301 systems was issued by the Health and Safety Executive (HSE) in the form of Guidance Note GS16[f] .This did not apply to the clean agents referred to above. Partly as a consequence of this, NEAG was tasked with reviewing a new American standard covering systems using clean agents, NFPA 2001. Among other things, NFPA 2001 contains requirements relating to their safe operation. The Standard's criteria are based largely, although not exclusively, on one specific toxic end-point the agents potential for cardiac sensitisation. For the majority of the agents covered by the standard, this is deemed to be the most likely toxic end point to produce the first adverse toxicological effect.

Owing to the apparent emphasis on cardiac sensitisation, NEAG had reservations about endorsing the adoption of these criteria in the UK. As a consequence, it recommended to HAG that a study be undertaken to assess the range of possible effects on human health of these new gaseous fire extinguishing agents. This report contains the findings of that study. It involved critical evaluation of the available toxicity data supplied by manufacturers* of the agents. As such, it is analogous to the assessment of halon 1301 undertaken by HSE in the early 1980s.

The assessment of the new agents was undertaken on behalf of HAG by a tripartite group of government and industry toxicologists and a respiratory physiologist. One organisation was sponsored by the manufacturers. The experts were required to assess the new agents against a protocol prepared for NEAG by HSE. This is reproduced as Appendix 1 to this report.

Further background information on the assessment process, the safe operation of gaseous fire extinguishing systems, and the replacements considered in this review is provided in Section 2 of this report. A brief summary of the findings of the experts is presented in Section 3. These findings were used by NEAG to establish a consensus opinion on the safe use criteria to be applied to the new agents. The recommendations that follow from this are outlined in Section 4.

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[f] GS 16 has been withdrawn.

*The term *manufacturer* is used in this report to also denote a distributor, who may for example have patent or agency rights, and is therefore responsible for introducing the product into the UK

This report does NOT address the following:

a. the suitability and effectiveness of the agents in extinguishing fires

b. health hazards posed by the storage, handling and use of clean agents at elevated pressures, whether as a liquid, gas or vapour.

Although not considered in detail, the following hazards have, to some extent, been taken into account in formulating the recommendations made in this report:

a. the toxic hazards posed by any decomposition products formed when a clean agent is in contact with flames or a hot surface

b. the toxic/asphyxiating hazards posed by combustion products from the fire and

any synergism with either:

i. the neat agent

ii. decomposition products.

The report does not address the environmental implications of using clean agents. Further guidance on this can be found in the *DTI Booklet Fire Fighting - Halon Phase Out: Advice on Alternatives and Guidelines for Users.*

NEAG does not purport to be an authority on the toxicological or physiological effects of chemicals on humans, although expert advice has been sought in formulating the recommendations made in this report. Nevertheless, the information upon which this review was based was supplied by others, namely the manufacturers of the agents. NEAG accepts no liability whatsoever for the accuracy of that information or any errors or omissions in the data supplied.

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2. BACKGROUND

Halons contribute to depletion of the ozone layer and, under the terms of the Montreal Protocol, production of halons was required to cease from the 1st January 1994. In view of this situation, there has been a great deal of activity by chemical manufacturers and fire equipment suppliers to develop replacement gaseous agents that are effective, clean, non-conducting and of low toxicity. These replacement agents are either other halocarbons or inert gases.

Custom and practice on the safe operation of systems utilising gaseous agents has evolved over a number of years and is largely dependent on the toxic risk of the agent. For most applications, precautions are required to permit people to escape before a discharge. These may include a time delay before discharge, a pre-discharge audible warning and facility to hold-off a discharge if more time is needed to escape. It is extremely rare for people to have to remain in an area during a gas discharge (some military applications are the exception). Exposure under other circumstances is likely to be inadvertent e.g. from a failure to escape before discharge commences or because of an unannounced accidental discharge. Such occurrences are, on the basis of current experience, rare.

NEAG considers that exposure to gaseous fire extinguishing agents should be avoided and that all personnel should evacuate the area before discharge. However, for a limited number of specialist applications there may be a need for people to remain inside the protected area during or after a discharge. These applications are outside the

scope of this report and are therefore not addressed.

Gaseous agents extinguish flames by a combination of mechanisms and this affects the concentrations required. They either reduce the oxygen level to a point that will no longer support flaming combustion (inert gases) or chemically interfere with the combustion process (halocarbons). Additionally, both classes of agent remove heat from the flame

Inert gas agents consist of either argon, or blends or argon and nitrogen, and one makes use of the addition of a low concentration of carbon dioxide (CO_2) to enhance respiration. They extinguish flaming fires by reducing the level of oxygen in the room typically to below 15%. To achieve this, a design concentration of the extinguishing agent equivalent to 35% of the room volume is normally required. For these agents, the bulk of the assessment by the three experts related to the risks posed by the oxygen deficient atmospheres.

Carbon dioxide, which has traditionally been used in fixed systems, also extinguishes fires by the same mechanism as the inert gas agents. However, CO_2 differs from inert gases in that it is toxic. The concentration needed to extinguish a fire will generate a hazardous atmosphere and may kill people if they remain in the protected space after discharge.

Halocarbon agents are more efficient at extinguishing flaming combustion than inert gases. They require a design concentration of between 5-20%. For these agents, the risks arise either from the inherent toxicity of the agent itself or from a reduction in the oxygen level.

The benchmark in the UK has been set by halon 1301 and, because of its low toxicity, it has been acceptable to use halon 1301 systems on automatic control to protect occupied areas provided that the concentration after discharge does not exceed 6%. This was based on good evidence from human exposure studies that halon 1301 concentrations above 10% produce significant CNS disturbances and cardiac effects. The restriction on automatic use to concentrations of 6% or less reflected these concerns. It was therefore an objective of the assessment to compare the toxic and asphyxiating hazards of the clean agent replacements with halon 1301, and to establish at what concentration the use of each of these agents is likely to be as safe as the use of halon 1301 at 6%.

The assessment process involved the submission, in confidence, of data relating to each of the toxic end points covered by the protocol. It was intended that all the experts should receive identical data sets. The manufacturers were requested to supply data that were already available and, as such, they were not required to undertake any new test work as part of this assessment.

In assessing the data, the experts were requested to:

- comment on how well the end points defined in the protocol had been evaluated
- where appropriate, provide the NOAEL and LOAEL values for each end point
- comment on the margin of safety in the agent's extinguishing design concentration and provide recommendations on acceptable safe use exposure

levels with reference to the benchmark set by halon 1301.

Reports were exchanged between the experts and a jointly agreed summary report was prepared for each agent. The wording of each of the summaries was agreed with the relevant manufacturer. The summary reports were then presented to NEAG and have formed the basis of the conclusions drawn, and recommendations made, in this report.

Six clean agent replacements for halon1301 were assessed. The agents and their manufacturers are as follows:

Agent	**Trade Name**	**Manufacturer**
Perfluorobutane	CEA 410	3M United Kingdom plc
HFC23 (trifluoromethane)	FE13	Du Pont (UK) Ltd
HFC 227ea (heptafluoropropane)	FM200	Great Lakes Chemical (Europe) Ltd
Blend of 52% Nitrogen 40% Argon and 8% CO_2	INERGEN	Wormald Ansul (UK) Ltd ADT Fire & Security Ltd
Blend of 50% Nitrogen and 50% Argon	ARGONITE	Ginge Kerr Ltd
100% Argon	ARGOTEC	Preussag Fire Protection Ltd

The typical design concentrations quoted in this report are those provided by the manufacturers. It was not possible within the timescale of the assessment and with the data available, to validate these concentrations.

3. SUMMARY OF ASSESSMENT FINDINGS

Inert Gases

The data submitted by each of the three inert gas manufacturers mainly comprised expert reviews and opinion on the expected physiological effects of inhalation of a mixture of air with the various compositions of argon, nitrogen and CO_2.

NEAG concurred with the experts' view that the inert gas agents and the halocarbon agents should be considered differently with regard to the hazards they pose. Argon and nitrogen, at atmospheric pressure, in the absence of hypoxia are inert, and CO_2 has well known physiological effects. It was not considered appropriate to compare the data

on the inert gases directly with the available toxicity data available on halon 1301.

It was concluded that people should not suffer adverse effects, due to hypoxia, provided that the following criteria are adhered to:

- the oxygen concentration must not fall below 10% at any time whilst people are present
- at oxygen concentrations between 12% and 10%, exposure should not exceed 1 minute
- at oxygen concentrations between 12% and 15%, exposure should not exceed 10 minutes.

In recognition of the presence of the CO_2 in one agent, and the beneficial effects of an increased inspired CO_2 concentration on blood oxygenation and cerebral blood flow, the criteria that should be adhered to in the case of this agent are different and are as follows:

- the oxygen concentration must not fall below 10% at any time whilst people are present.
- at oxygen concentrations between 12% and 10%, exposure should not exceed 2 minutes
- at oxygen concentrations between 12% - 15%, exposure should not exceed 20 minutes
- final CO_2 levels should be between 2.5% and 5%.

In a non-fire situation, NEAG was clear that there was an advantage in adding CO_2 to the inert gas mixture. Although detailed evaluation of the likely hazards of any decomposition products or products of combustion was outside the scope of the assessment, the implications of the presence of CO_2 in a fire situation were considered. It should be noted that, in a fire situation, the elevated CO_2 level will help to maintain normal cognitive function, due to positive effects on blood oxygen saturation and cerebral blood flow and hence should assist in the egress from the room. However, the induced increase in ventilation and possible reduction in breath-hold time, **may** enhance the uptake by the body of toxic materials from the fire. The relative importance of these two factors is difficult to predict and will depend on the particular situation.

See 4. Recommendations

Halocarbons

For the halocarbon agents, direct comparison of the toxicological properties of the agent with halon 1301 was attempted. This was not always achievable owing to inadequacies in the content and quality of the data submissions from the manufacturers. Where the data available were incomplete, or not seen by all the experts, it was necessary to make a judgement from summary data. While this does not

necessarily imply any particular concern for these substances, the data has not therefore been assessed in as great detail as the data for the other halocarbon.

The three halocarbon agents were assessed against the six toxic end points in the protocol and, where the information was available, the "no effect" levels were identified. These are presented in Table 1.

For FE13, the limiting toxic effect was considered most likely to be hypoxia due to oxygen deficiency at high use concentrations.

For CEA 410, the limiting effect was again considered to be hypoxia due to oxygen deficiency at high use concentrations.

For FM200, the critical effect was that of cardiac sensitisation, and the limit of 9% was established from the studies provided.

The toxicological assessment of the halocarbons has not addressed the potential for exposure to the decomposition products of these agents. See 4. Recommendations

TABLE 1 COMPARISON OF HALOCARBON AGENTS WITH HALON 1301

AGENT	TYPICAL USE CONCENTRATION	ACUTE EFFECTS LC50 (4HR)	CNS EFFECTS	CARDIAC SENSITISATION	RESPIRATOR SENSITISATI
HALON 1301	5%	>80% @20% 0_2	HUMAN: 1%-7% MILD EFFECT >10% SIGNIFICANT EFFECT DOGS & PRIMATES: MILD EFFECT @ 20%	DOG: NOAEL 5% LOAEL 7.5% EC50 20%	NOT TESTED
CEA 410	6.25%	>80% @ 20% 0_2	DOG: NO EFFECT @ 40% RAT: NO EFFECT @ 79% - 20% O_2	DOG: NO EFFECT @40%	NOT TESTED
FE13	16%	>66% (4)	HUMAN: NOAEL 30% LOAEL 40% (2) RATS: MILD	DOG: NO EFFECT @50%	NOT TESTED

			EFFECT @19% (2)		
FM200	7%	>80% @ 20% O_2	DOG: NO EFFECT @ 15% MILD EFFECT @ 30%	DOG: NOAEL 9% LOAEL 10% -10.5% EC_{50} 14-30%	NOT TESTED

(1) This effect is not considered of significance for this agent

(2) Information obtained from abstract. Full report was not available at time of assessment

(3) Manufacturer does not consider this end-point to be of concern

(4) Insufficient detail provided to know if the atmosphere at 66% was O_2 enriched

4. RECOMMENDATIONS

Following consideration of the findings from the experts, NEAG sought to establish a consensus view on safe use criteria for the clean agent replacements covered by the assessment. Account was taken of the benchmark set by halon 1301. In particular, it was considered appropriate to attempt to establish the concentrations above which it would be necessary to impose engineering controls to prevent automatic operation of a system while people are present, which, for halon 1301, is 6%. These concentrations are presented in Table 2. For comparison, the typical design concentrations provided by the manufacturers are also included.

It is important to emphasise that the safe use criteria established by NEAG were based on the understanding that only short term (i.e. a few minutes) inadvertent exposure to an agent is likely. They do not apply where deliberate or longer term exposure is either intended or likely. Any such situation would need to be justified by a formal risk assessment, and it is likely that safety equipment such as breathing apparatus would need to be readily available.

The need for a gaseous extinguishing system to be on automatic control while people are present should be considered as part of a risk assessment when specifying/designing a system.

Although Table 2 recommends the maximum concentrations for systems to be on automatic control while people are present, the amount used should be the minimum necessary to extinguish the fire effectively.

The effect of toxic and corrosive products resulting from the breakdown of extinguishing gases within the flames, and from the fire itself, are not considered in this report. The concentration of toxic products from the fire depends, among other things, upon the duration of burning which, because of their longer discharge times, will generally be longer with the inert gases than with the halocarbons. The inert gases

themselves will not add to the concentration of toxic products. The application of the halocarbons to flames results in the production of toxic breakdown products, mainly hydrogen fluoride, which is highly toxic and corrosive. The short discharge times and rapid fire control achieved by these agents should minimise the quantity of toxic products produced which, however, will still be likely to be greater than would be the case with halon 1301.

Although engineering standards for clean agent systems have not yet been produced in the UK, it is considered that the engineering controls and safety precautions stipulated for halon 1301 systems should apply to clean agent replacements. For example, clean agent systems should incorporate:

- a pre-discharge time delay sufficient to allow escape prior to a discharge
- warning signs, status indicator lamps, hold switches and a means of isolation to permit maintenance to be carried out safely
- It should be possible to exit the protected area without the use of a key should there be a need to overcome locking mechanisms.

Where it is required to lock the system off, a changeover device to set the system from `automatic/manual' to `manual only' mode should be provided. Changeover should preferably be achieved automatically on entry, e.g. by means of door interlocks.

TABLE 2A - SAFE USE CRITERIA FOR HALOCARBON REPLACEMENTS FOR HALON 1301

AGENT	TYPICAL DESIGN CONCENTRATION	MAXIMUM RECOMMENDED CONCENTRATION FOR SYSTEMS ON AUTOMATIC CONTROL FOR OCCUPIED AREAS
HALON 1301 (6)	5%	6% (5)
CEA 410 (1) & (4)	6.25%	29%
FE13 (3) & (4)	18%	23%(2)
FM200	7%	9%

1. Full Data Only Supplied To One Expert
2. This figure was raised from 17% as originally reported following further Evaluation of data by two of the original three toxicologists
3. Data available for review consisted only of copies of correspondence and Data sheets. No full reports other than that for cardiac sensitisation Potential were available for review
4. No data available on developmental toxicity
5. Special high risk applications eg inerting for explosion suppression may Require use of higher concentrations in occupied areas

(6) For comparison

TABLE 2B - SAFE USE CRITERIA FOR INERT GAS REPLACEMENTS FOR HALON 1301

AGENT	TYPICAL DESIGN CONCENTRATION	MINIMUM RECOMMENDED OXYGEN CONCENTRATION FOR SYSTEMS ON AUTOMATIC CONTROL FOR OCCUPIED AREAS
ARGOTEC ARGONITE	DESIGN CONCENTRATION OF 37.5% - 40% EQUIVALENT TO A FLOODING FACTOR 47% - 51% (4) RESULTING IN A 0_2 CONCENTRATION BETWEEN 13.1-12.6% IN THE CASE OF INERGEN, A CO_2 CONCENTRATION BETWEEN 3% - 3.2%	SHOULD NOT BE BELOW 12% (2) UNLESS THE ROOM CAN BE EVACUATED IN 60 SECONDS (3) O_2 MUST NOT BE BELOW 10% (1)

INERGEN (5)		

(1) Equivalent to a flooding factor of 74% and a design concentration of 52%

(2) Equivalent to a flooding factor of 56% and a design concentration of 43%

(3) 120 seconds in the case of INERGEN

(4) The flooding factor is the amount of gas going into a room during the discharge.

The resulting concentration of agent is the design concentration

(5) The resultant CO_2 concentration must be between 2.5% - 5%

It is again emphasised that all occupants should evacuate the protected area immediately on hearing the alarm, and they should be actively discouraged from remaining in, or returning to, the protected area when gas is present. Areas must be certified as safe before re-entry is permitted.

Care should be taken to ensure that people with known medical problems, such as overt cardio-respiratory disease, should not be exposed to oxygen deficient atmospheres or atmospheres containing any fire fighting agent that would put them at risk.

Definitions and Abbreviations

Ames Test — A bacterial test to investigate the potential of a substance to cause genetic damage. In theory, such damage could lead to cancer.

Cardiac Sensitisation — Increased response or sensitivity of the heart to the stimulant effect of adrenaline circulating in the body. Sensitisation could lead to irregularities in the heartbeat which could potentially be life-threatening in extreme cases.

CNS	Central Nervous System
CO_2	Carbon dioxide
EC50	Effective Concentration 50 (the concentration at which 50% of the animals would show a positive effect)
EPA	United States Environmental Protection Agency
GS16	Gaseous Fire Extinguishing Systems: Precautions for Toxic and Asphyxiating Hazards (HSE publication)
HAG	Halon Alternatives Group
HSE	Health & Safety Executive
IVC	(Invitro cytogenetic test) using isolated/cultured mammalian cells to investigate the potential of a substance to cause genetic damage. In theory, such damage could lead to cancer.
LOAL	Lowest Observed Adverse Effect Level
NEAG	New Extinguishants Advisory Group (Also known as Sub-Group B)
NFPA 2001	Standard on Clean Agent Fire Extinguishing Systems 1994 Edition.
NOAEL	No observed Adverse Effect Level
SNAP	Significant New Alternatives Policy

(USA - EPA)

APPENDIX 1 - PROTOCOL FOR TOXICOLOGICAL EVALUATION OF FIRE EXTINGUISHANTS

The use of halon 1301 is being phased out as a result of the implementation of the Montreal Protocol on substances that deplete the ozone layer. However, a number of other agents are being put forward as replacements. For each agent there is obvious potential for human exposure and the agents may be in use for many years into the future. Hence, before the extinguishants are used, an assessment must be made of their potential health effects. At first sight, the attached protocol may seem lengthy and onerous but it is intended to ensure that the health effects that may cause concern under the likely conditions of use are identified so that the appropriate action, if any, may be taken.

The test battery proposed for the toxicological evaluation of halon replacement agents is intended to cover those end points which are of concern in relation to the types of human exposure anticipated. The exposure scenarios which are anticipated are:

- a single short duration (10 minute) exposure in the event of a fire or accidental release of the agent
- a single long duration (up to a few hours) exposure, such as may occur when a room or building is re-occupied following release of the agent and a residual amount remains in the atmosphere, or as may be experienced by occupiers of adjacent rooms or properties into which the agent has leaked
- repeated exposure such as may be experienced by people regularly using the materials, such as those engaged in filling containers or in regular maintenance operations.

PROTOCOL FOR TESTS ALREADY CARRIED OUT

On this basis the following toxicological end points of concern for human exposure should be addressed. The test concentrations used should include the proposed concentration at which the extinguishant shall be used but should also extend to higher concentrations including, where possible, concentrations at which substance-related effects are observed. The choice of test concentrations should ensure that effects of concern do not occur at concentrations in use and should provide a picture of the margin of safety indicating the concentration at which effects do begin to occur.

Acute inhalation toxicity

The acute toxicity of the substance by inhalation should be assessed by any internationally recognised regulatory test method (preferably as given guidelines). The tests should meet the minimum requirements laid out in the regulatory guidelines. The potential of the agent to cause skin, eye and respiratory tract irritation should also be assessed within the acute inhalation study, as should be potential for the agent to cause asphyxiation by dilution of the oxygen in the atmosphere. The exposure duration for the acute inhalation test, specified in the regulatory guidelines, is four hours. The use of a different exposure period may be justified on the basis of the expected human exposure period.

Central nervous system (CNS) effects

The potential of the agent to cause CNS effects should be addressed, since such effects in humans may affect the ability to escape or to perform essential operational tasks. There are no standard regulatory guidelines for testing for CNS effects in animals. Animals should be exposed to the test substance for an exposure period relevant to the anticipated human exposure period. The animals should be observed closely for any clinical signs which could be indicative of a CNS effect, e.g. changes inactivity level, changes in gait, indication of an anaesthetic effect, tremors, convulsions, coma. It may also be helpful to conduct behavioural studies, e.g. rotarod test, grip strength test.

Cardiac sensitisation

There is no internationally recognised regulatory test method for cardiac sensitisation in animals. However, a protocol is available in the published literature (Reinhardt et al, 12971) which provides the basic principles for cardiac sensitisation testing.

Respiratory sensitisation

No recognised test method for this end point is currently available. However, prediction of the potential of a substance to cause respiratory sensitisation in humans should be attempted, based on Structural Activity Relationship (SAR) considerations and from experience with structurally similar compounds.

Genotoxicity

In theory, it is possible that genetic damage may occur from a single exposure to a genotoxic substance (the `one-hit' theory). The potential for the halon replacement agent to cause genotoxic damage in mammalian cells in vivo needs therefore to be addressed. Initially, testing should be conducted in vitro; positive results in such tests should normally be explored further in vivo. The testing strategy should follow COM guidelines or the 7th amendment guidelines.

Reproductive toxicity

Again, in theory, reproductive effects, particularly developmental effects, may occur following a single exposure to a substance toxic to reproduction. The potential for the halon replacement agent to cause development effects, since these are of primary concern, should be addressed.

In assessing the adequacy of the available animal data, the quality of the study will be taken into account, as well as the reliability with which the data may be extrapolated to the human situation. Information from human experience will be given greater weight than corresponding animal test data.

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