SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

oxydiethylene dinitrate

EC No 211-745-8

CAS No 693-21-0

Evaluating Member State(s): Italy

Dated: 19 November 2019

Evaluating Member State Competent Authority

MSCA Italy National Institute of Health on behalf of Ministry of Health
Viale Regina Elena, 299 - 00161 Rome, Italy in cooperation with Italian National Institute for Environmental Protection and Research (ISPRA). Via Brancati, 48 - 00144 Rome, Italy

Tel.: +390649902061
FAX: +390649902286
Email: leonello.attias@iss.it

Year of evaluation in CoRAP: 2016

Member State concluded the evaluation without any further need to ask more information from the registrant(s) under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

Oxydiethylene dinitrate was originally selected for substance evaluation in order to clarify concerns about:

- suspected Carcinogen
- suspected Reproductive toxicant
- potential endocrine disrupter
- suspected PBT/vPvB
- high risk characterisation ratio

During the evaluation also other concern was identified. The additional concern was:

- suspected Mutagen

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	Tick box
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures:	
No need for regulatory follow-up action at EU level	X

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

Not applicable.

4.1.1. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2

REASON FOR REMOVED CONCERN The concern could be removed because	Tick box
Clarification of hazard properties/exposure	X
Actions by the registrant(s) to ensure safety, as reflected in the registration dossiers(e.g. change in supported uses, applied risk management measures, etc.)	

The evaluating MSCA has performed the evaluation of the substance oxydiethylene dinitrate for both human health and environmental aspects.
Oxydiethylene dinitrate has originally been selected for substance evaluation in order to clarify specific concerns such as suspected C, suspected R, high RCR, suspected PBT/vPvB, potential endocrine disruptor with an additional concern of suspected M raised during the evaluation.
However, since this substance is used in explosives products and is itself characterized by extremely high explosive properties, performing laboratory studies with this substance is extremely dangerous. For this reason the adaptation arguments given by the registrant(s) to not perform the tests are considered as met.
Moreover for oxydiethylene dinitrate only industrial uses are foreseen and the uses are under strictly controlled industrial conditions.
For these reasons the evaluating MSCA concluded the process without the need to request further information.

5.2. No need for regulatory follow-up at EU level

The substance is used only at industrial sites and no consumer use leading to a significant exposure has been identified. The substance is used in stricted controlled industrial conditions and the RMM and OC, as reported in the CSR, are considered sufficient to control the risks. Moreover, the evaluating MSCA noted that for glycerol trinitrate (EC 200-240-8), the substance used for read-across, an indicative Occupational Exposure Limit Value of 0,01 ppm is available in the EU, based on the acute effect of the substance. Due to the similarity of the intrinsic properties of these substances, a similar OELV could be used also for oxydiethylene dinitrate.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

Part B. Substance evaluation

7. EVALUATION REPORT

The Substance evaluation has started on March 2016.

7.1. Overview of the substance evaluation performed

Oxydiethylene dinitrate was originally selected for substance evaluation in order to clarify concerns about:

- suspected Carcinogen
- suspected Reproductive toxicant
- high risk characterisation ratio
- suspected PBT/vPvB
- potential endocrine disruptor

additional concern raised during the evaluation:

- suspected Mutagen

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Endpoint 1 Suspected Carcinogen	The initial concern on potential carcinogenic properties cannot be clarified based on the available data. Due to the explosive nature of the substance, exposure to the substance will be limited and performing laboratory studies extremely dangerous and is not recommended. Therefore, as reported above the evaluating MSCA accepted the adaptation arguments given by the registrant(s) to not perform the tests. In addition, only industrial uses are foreseen and the uses are under strictly controlled conditions. No further action is forseen (see also section 5.1 for details).
Endpoint 2 Suspected Reproductive toxicant	Initial concern on reproductive toxicity properties cannot be clarified based on the available data but the explosive nature of the substance makes extremely dangerous to perform the laboratory studies. In addition, only industrial uses are foreseen and the uses are under strictly controlled conditions. Therefore no further action is foreseen (see section 5.1).
Endpoint 3 Suspected PBT/vPvB	Initial concern on PBT/vPvB properties is not clarified but the explosive nature of the substance means that further testing of PBT properties would be dangerous and is not recommended. In addition, only industrial uses are foreseen and the uses are under strictly controlled conditions. No further action (see section 5.1).
Endpoint 4 Potential endocrine disruptor	Initial concern on potential endocrine disrupting properties is not clarified. Due to

	the explosive nature of the substance, performing laboratory studies will be extremely dangerous and is not recommended. In addition, only industrial uses are foreseen and the uses are under strictly controlled conditions. No further action (see section 5.1).
Endpoint 5 Suspected Mutagen	Positive results *in vitro* gene mutation and rejection of *in vivo* genotoxicity read-across raised an additional concern for genotoxicity/mutagenicity. In particular the read-across is considered plausible by evaluating MSCA but not acceptable in the present form. Due to the explosive nature of the substance, performing laboratory studies will be extremely dangerous and is not recommended. In addition, only industrial uses are foreseen and the uses are under strictly controlled conditions. No further action (see section 5.1).

7.2. Procedure

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected Carcinogen, suspected Reproductive toxicant, potential endocrine disrupter,suspected PBT/vPvB, high RCR, oxydiethylene dinitrate was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2016. The updated CoRAP was published on the ECHA website on 22 March 2016. The competent authority of Italy (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

In accordance with Article 45(4) of the REACH Regulation, the evaluating MSCA carried out the evaluation of oxydiethylene dinitrate based on the information in the registration(s) and other relevant and available information. In the course of the evaluation, the evaluating MSCA identified additional concerns regarding genotoxicity.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision under Article 46(1) of the REACH Regulation to request further information. It subsequently submitted the draft decision to ECHA on 22 March 2017.

On 02 June 2017 comments to the draft decision were provided by the registrant(s). The evaluating MSCA decided that in consideration of the explosive properties of the registered substance, difficulty to conduct experimental testing and limited exposure of the registered substance (industrial use as explosive under strictly controlled conditions), no further information would be requested to clarify the concern(s). On that bases the evaluating MSCA concluded that the current available information is sufficient to address the concerns identified. Consequently the substance evaluation decision-making process was terminated and the substance evaluation process concluded.

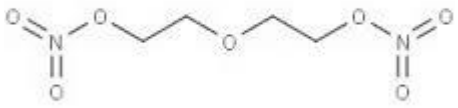
7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	Oxydiethylene dinitrate
EC number:	211-745-8
CAS number:	693-21-0
Index number in Annex VI of the CLP Regulation:	603-033-00-4
Molecular formula:	C4H8N2O7
Molecular weight range:	--
Synonyms:	--

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Liquid
Vapour pressure	0.007 Torr at 22.4°C
Water solubility	3900 mg/L at 25 °C
Partition coefficient n-octanol/water (Log Kow)	Log Pow 1.13
Flammability	--
Explosive properties	Detonation velocity at density: 6.75 km/s at 1.38 g/cm3 Explosion temperature at 5 s: 240°C. Explosive
Oxidising properties	--
Granulometry	--
Stability in organic solvents and identity of relevant degradation products	--
Dissociation constant	--

7.5. Manufacture and uses

7.5.1. Quantities

Table 6

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☒ 100 – 1000 t	☐ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

This substance is manufactured and/or imported in the European Economic Area in 100 - 1 000 tonnes per year.
This substance is used in explosives.
ECHA has no registered data on the types of manufacture using this substance.
This substance is used in the following products: explosives.
Release to the environment of this substance can occur from industrial use: formulation in materials.

Table 7

USES	Use(s)
Uses as intermediate	--
Formulation	Formulation Propellants and explosives
Uses at industrial sites	Use Propellants with oxydiethylene dinitrate as plasticizer
Uses by professional workers	--
Consumer Uses	--
Article service life	--

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

The substance is currently listed on Annex VI of CLP Regulation ((EC) No 1272/2008).

Table 8

HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008)							
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Spec. Conc. Limits, M-factors**	**Notes**
				Hazard Class and Category Code(s)	**Hazard statement code(s)**		
603-033-00-4	oxydiethylene dinitrate diethylene glycol dinitrate digol dinitrate	211-745-8	693-21-0	Expl. 1.1 Acute Tox.2* Acute Tox.1 Acute Tox.2* STOT RE 2* Aquatic Chronic 3	H201 H300 H310 H330 H373** H412		

7.6.2. Self-classification

The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:

Unst. Expl. H200

7.7. Environmental fate properties

7.7.1. Degradation

Experimental data on abiotic and biotic degradation are present in the registration dossier. The data are summarized from studies evaluating the transport and transformation of Organic Chemicals. The used test protocols were described by Mill, T. (1982) and developed in SRI International laboratory (Menlo Park, California).

From the results of hydrolysis key study (reliability 2 and not in compliance with GLP) the registrant(s) affirm that the hydrolysis of substance is found to be extremely low under most environmental conditions.
The evaluating MSCA supports the registrant(s)'s conclusion that the substance is considered hydrolytically stable.

The results of phototransformation in water key study (reliability 2 and not in compliance with GLP) show the half-lives ranges from 15 days (summer) to 59 days (winter). The evaluating MSCA can support the conclusion of the study: the environmental fate of oxydiethylene dinitrate would be dominated by photolysis.
Regarding screening tests on biodegradation in water, the registrant(s) provided two biotransformation rate studies. In the key study (Spanggord, R.J., 1987), the biotransformation of oxydiethylene dinitrate proceeded with a second-order rate constant of 3.9×10^{-11} mL $cell^{-1}$ h^{-1}, corresponding to a half-life of about 2 years in a typical surface water (740 days). Microorganisms obtained from the production site (RAAP, Radford Army Ammunition Plant Radford, VA) treatment plant effluent were used as the source of inoculum and ethanol was used as a supplemental organic nutrient.
A supporting biotrasformation study (Spanggord, R.J., 1985) was conducted with samples of local pond water (Searsville Pond, Woodside, CA) and waters obtained from RAAP, including the biotreatment plant's aeration lagoon water, rotating biological contactor effluent, anaerobic sludge, and New River (the river in which RAAP waste streams discharge) water, under aerobic and anaerobic conditions and, in some cases, with supplemental organic nutrients (ethanol, glucose and yeast extract). The local pond waters did not show a significant decrease in oxydiethylene dinitrate concentration during the 40 days of incubation. One exception was the water with added organic nutrients, under anaerobic conditions. The biotransformation half-life in waters from RAAP ranged from 5 days (in the presence of ethanol as a very efficient substrate for microorganisms) to greater than 40 days, depending on the amount of organic nutrients/microbes present. In the New River water alone, loss of oxydiethylene dinitrate was only 14% after 50 days. These results suggest that oxydiethylene dinitrate may be biotransformed with extra organic nutrients and ethanol seems to be an efficient cometabolic substrate for the RAAP organisms.

A sediment-mediated transformation study (Spanggord, R.J., 1985) was provided by the registrant(s) as key simulation test. The study was conducted using sediments from RAAP (collected from the New River approximately 500 meters below the treatment plant discharge) and from local Searville Pond. Under anaerobic conditions, losses of oxydiethylene dinitrate in sediments were complete in ≤ 8 days and occurred at the same rate in non-sterile and sterile samples. Under aerobic conditions, consumption of oxydiethylene dinitrate in sediments was slower and sterilization reduced but not eliminated the transformation. While some of the loss in the aerobic samples can be attributed to biotransformation, the losses under anaerobic conditions appear to be abiotic and the phenomen can be attributed to chemical reduction. The results of the study suggest that while the sediment-mediated reduction probably does not contribute greatly to the overall fate of oxydiethylene dinitrate in most surfaces waters because of its low Kp, reduction, not quantified in the study, is a possible process in removing oxydiethylene dinitrate near the sediment-water interphase.

In the supporting simulation study (Cornell, J.H., 1981) submitted by the registrant(s), oxydiethylene dinitrate was challenged by microorganisms under batch and continuous culture under aerobic conditions for 6 days. Activated sludge inocula from a local domestic sewage treatment plant, mineral salts, and ethanol or glucose as an additional carbon source were used. The study did not follow any guideline. The degradation of oxydiethylene dinitrate proceeded via a sequential stepwise hydrolytic cleavage of the nitrate groups resulting in the formation of the partially nitrated parent glycols. No information about oxydiethylene dinitrate concentration, density of inocula, degradation rate and removal percentage was provided.

Regarding biodegradation in soil the registrant(s) provided a key study (Spanggord, R.J., 1985), carried out on soil collected from the land near RAAP, in aerobic/anaerobic

conditions. The biotransformation of oxydiethylene dinitrate appears to be very slow in soil under aerobic conditions (after 5 weeks, only 16 and 24% of the initial oxydiethylene dinitrate was lost in sterile and nonsterile soil samples, respectively). No transformation was observed in study on soil-water mixture in sterile samples or in aerobic–nonsterile samples, while oxydiethylene dinitrate was totally transformed after 21 days under anaerobic-nonsterile conditions.
On the basis of these results, the registrant(s) consider oxydiethylene dinitrate as inherently biodegradable in water and state that it is not expected to be persistent in the environment.
The evaluating MSCA considers that the information and results available from the studies provided by the registrant(s) are not sufficient to conclude that oxydiethylene dinitrate is not persistent in the environment. Indeed, the studies do not follow standard guidelines, are not in compliance with GLP, are not sufficient detailed on study design and result information (density of inoculum, degradation rate, fraction of non-extractable residues, mass balance during and at the end of study, identification and concentration of transformation product) and most of them are carried out with microorganisms and environmental media collected from the area of production site of the substance. Therefore it is not possible to exclude a pre-adaption of the microorganisms through previous exposure to oxydiethylene dinitrate. All the screening and simulation tests used in the assessment of the persistence shall be performed with not pre-adapted microorganisms since the adaptation of the microorganisms increase the biodegradation potential, compared to natural environments. In addition, the test results show that when microorganisms not pre-adapted are used, the biotransformation of oxydiethylene dinitrate is slow and in the case the biotransformation of the substance occurs, it is due to the addition of extra organic substances. Finally, in all studies provided as simulation tests, the concentration of oxydiethylene dinitrate used is in the range 10-20 ppm, which is too high for these types of tests, where the normally used concentration in standard OECD simulation test guidelines ranges from less than 1 µg/L to 100 µg/L.

The evaluating MSCA notes that on the basis of QSAR estimations (BIOWIN v.4.10, EPISuite), oxydiethylene dinitrate is predicted as not readily biodegradable with the exception of one QSAR model (BIOWIN 3), whose result is borderline (2.75). Furthermore, in BIOWIN (EPISuite) the following criterion is reported: if Biowin 3 (ultimate degradation) result is "weeks" or faster (i.e. days or days to weeks) AND Biowin5 (MITI linear model) probability is ≥ 0.5, then the prediction is YES (readily biodegradable). If this condition is not satisfied, the prediction is NO (not readily biodegradable). For oxydiethylene dinitrate the result obtained with Biowin 3 is weeks, and the result of Biowin 5 is < 0.5, therefore, the prediction is NO (the substance does not readily biodegrade).
According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT/vPvB assessment, June 2017, the following QSAR based screening criteria can be used for identifying substances screening for P and vP: BIOWIN 2 <0.5 and BIOWIN 3 <2.25 (- 2.75) or BIOWIN 6 <0.5 and BIOWIN 3 <2.25 (- 2.75), i.e. for substances fulfilling this algorithm but BIOWIN 3 indicates a value between 2.25 and 2.75 more degradation relevant information is generally warranted in relation to the PBT testing strategy.
For oxydiethylene dinitrate, BIOWIN 2 and 6 give a result <0.5 and BIOWIN 3 gives a result of 2.75, therefore, this substance should be considered as a borderline case to examine carefully, and more information about the degradation would be necessary.
Summarising, the biodegradation studies on the registered substance and results from the QSAR models indicate a concern for persistency but do not allow to conclude on the persistence of oxydiethylene dinitrate.
However, due to the explosive nature of oxydiethylene dinitrate, performing laboratory studies would be extremely dangerous and is not recommended. In addition, only industrial uses are foreseen and the uses are under strictly controlled conditions. For these reasons, the evaluating MSCA concludes that no further information needs to be required under this substance evaluation.

7.7.2. Environmental distribution

For oxydiethylene dinitrate in IUCLID file and CSRs there is no distribution modelling provided.
The registrant(s) provide a key study for adsorption carried out on sediment (reliability 2 and not in compliance with GLP). The Koc values at 20 °C were calculated to be 100 and 118, using EPA sediment 5 and 18 respectively. The evaluating MSCA can support the conclusion that the substance has a limited sorption.
The registrant(s) provide also a supporting study on volatilisation (not in compliance with GLP). The result is a very low Henry´s constant.
The registrant(s) conclude that the environmental fate of oxydiethylene dinitrate involves mainly the water phase. On the basis of high water solubility, low values of the Henry's constant and low soil adsorption, the evaluating MSCA can support this conclusion.

7.7.3. Bioaccumulation

Although oxydiethylene dinitrate shows a low potential for aquatic bioaccumulation, the estimated log Koa of 5.78 indicates that the substance could bioaccumulate in air-breathing organisms.

Aquatic bioaccumulation

The Registrant(s) provided the following justification for data waiving: "In accordance with column 2 of REACH Annex IX, the Bioaccumulation study (required in section 9.3.2) does not need to be conducted as the substance has a low potential for bioaccumulation (average Kow is 9.6 +/- 0.5)".
The Log Kow (log Kow = 0.98 at 25 °C) is below the screening threshold for aquatic organisms of Log Kow>4.5 referred to in ECHA Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT/vPvB assessment June 2017.
The evaluating MSCA can support the conclusion on low potential for aquatic bioaccumulation, also based on estimated aquatic BCF of 3.162 L/Kg (EPIWIN v.4.10, EPISuite).

Bioaccumulation in air-breathing organisms

Despite the conclusions regarding aquatic bioaccumulation, and a low value of log Kow (0.98 at 25 ° C, well below the triggering value of 4.5), the estimate of log Koa made with KOAWIN v1.10 (EPIWEB) on the registered substance, oxydiethylene dinitrate, gave a value of 5.78. This value has to be further clarified to assess bioaccumulation potential in air-breathing organisms, including mammals.
In fact, equivalent to log Kow for aquatic organisms, log Koa (octanol-air partition coefficient) can be used as a screening criterion for bioaccumulation in air-breathing organisms. An efficiently absorbed, non-biotransformed neutral organic chemical with a log Koa > ~5 or > ~6 in combination with a log Kow > ~2 has the potential to biomagnify in terrestrial food chains and air-breathing marine wildlife as well as in humans (Gobas et al., 2009). These partitioning property combinations relate to biomagnification potential only when predicated by the assumptions of high chemical absorption efficiency from the diet and no biotransformation after absorption and negligible active transport (in or out). In particular, considerations for absorption efficiency and biotransformation rates are thus also necessary for bioaccumulation assessment.
In a few words, in addition to the right combination of values of log Kow and log Koa, there must be the further condition that the substance should not be rapidly metabolized. Therefore, it becomes necessary to evaluate data on the toxicokinetics. However, the data received does not contain valuable information on toxicokinetics (see 7.9.1 Toxicokinetics). Overall, the information provided by the Registrant(s) is not sufficient to exclude potential bioaccumulation in air-breathing-organisms.
However, due to the explosive nature of oxydiethylene dinitrate, performing laboratory studies would be extremely dangerous and is not recommended. In addition, only industrial

uses are foreseen and the uses are under strictly controlled industrial conditions. For these reasons, the evaluating MSCA concludes that no further information needs to be required.

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

7.8.1.1. Fish

Short term toxicity

The Registrant(s) provided a result of a reliable test conducted on the registered substance indicating an LC_{50} greater than 100 mg/L for freshwater fish species.
A 96h LC_{50} value of 258 mg/L (measured concentration) was determined for the effects of the test substance on mortality of *Lepomis macrochirus* in accordance with ASTM E 729-80. This study was used for the purpose of CSA.
Based on the available information, no short-term toxicity hazard for fish has been identified, the evaluating MSCA can support the conclusion on this endpoint.

Long term toxicity

The Registrant(s) provided two results of reliable tests conducted on the read-across substance glycerol trinitrate, indicating a NOEC in the range of 0.01-1 mg/L for freshwater fish species.
The lowest 60d NOEC value of 0.03 mg/L (measured concentration) was determined for the effects of the glycerol trinitrate on the growth (dry weight) of *Oncorhynchus mykiss* in accordance with ASTM Draft 10 early life-stage toxicity tests with fish. This study was used for PNEC derivation by the Registrant(s), but not used for classification.
The evaluating MSCA cannot support the read-across from glycerol trinitrate to assess the chronic toxicity, as the acute results for glycerol trinitrate and oxydiethylene dinitrate on *Oncorhynchus mykiss* are not comparable, being glycerol trinitrate more toxic than oxydiethylene dinitrate (96h LC_{50} of 1.9 mg/L for glycerol trinitrate and 96h LC_{50} of 284.1 mg/L for oxydiethylene dinitrate).
Based on the available information, the evaluating MSCA cannot conclude on a long-term toxicity hazard for fish, as the chronic toxicity results on fish from the read-across substance glycerol trinitrate are not supported.

7.8.1.2. Aquatic invertebrates

Short term toxicity

The Registrant(s) provided a result of a reliable test conducted on oxydiethylene dinitrate, indicating an LC_{50} = 90.1 mg/L (based on measured concentrations; mortality effect) for *Daphnia magna* (ASTM 1980 [ASTM E729-80], static).
Based on the available information, no short-term toxicity hazard for invertebrates has been identified, the evaluating MSCA can support the conclusion on this endpoint.

Long term toxicity

The Registrant(s) provided a result of a reliable test conducted on the read-across substance glycerol trinitrate , indicating a NOEC (7d) = 3.23 mg/L (based on measured concentrations; neonate productioneffect) for *Ceriodaphnia dubia* (proposed ASTM method for 3-brood renewal toxicity test, Draft 3, static). This study was used for the purpose of CSA.
The evaluating MSCA can support the read-across from glycerol trinitrate, as the acute results for glycerol trinitrate and oxydiethylene dinitrate on Daphnids are comparable (48h LC_{50} of 17.83 mg/L for TNG and 48h LC_{50} of 90.1 mg/L for oxydiethylene dinitrate).

Based on the available information, no long-term toxicity hazard for invertebrates has been identified, the evaluating MSCA can support the conclusion on this endpoint.

7.8.1.3. Algae and aquatic plants

The Registrant(s) provided an experimental key study (Fisher, D.J. 1987b) with reliability 2, static on *Selenastrum capricornutum* exposed to oxydiethylene dinitrate.
A 5-day EC50 value of 39.1 mg/L, based on maximum dry weight (standing crop) of *Selenastrum cap.* (95% asymmetrical confidence limits = 28.8–52.9 mg/L) was determined; this value was used for CSA and C&L by the Registrant(s).
This algal toxicity study was performed according to GLP and following non-standard guideline (*Payne, A.G. and Hall R.H. 1979; Miller, W.E. et al.1978*). As indicated by the Registrant(s), the test is based on the *Algal Assay Procedure* (Bottle Test) (EPA-600/9-78-018) that can be considered acceptable, well-documented and fulfilling basic criteria for toxicity assessment. The study is adequately described and in accordance with the basic conditions for the validity of test for algal toxicity assessment.
The algal study is a short term test although it provides both acute and chronic endpoints. The Registrant(s) also reported that, based on the results, *Selenastrum cap*. is the most sensitive species tested with oxydiethylene dinitrate. Moreover, in this Algal assay: Bottle test the measure used to describe algal growth is the maximum dry weight mg l^{-1} (standing crop) produced during the 14-day incubation period; then, the Registrant(s) also indicated that, even if not directly comparable to the acute toxicity data, algal result gives an indication of possible chronic effect levels for oxydiethylene dinitrate.
The data submitted are suitable for evaluation of algal toxicity. Following the assessment of information from registration dossier, the evaluating MSCA concludes that there is no concern for this endpoint.

7.8.1.4. Sediment organisms

No data available for the registered substance oxydiethylene dinitrate. The tonnage band for the substance does not include long-term studies on sediment organisms.

7.8.1.5. Other aquatic organisms

No data available for the registered substance oxydiethylene dinitrate.

7.8.2. Terrestrial compartment

The Registrant(s) provided a data waiving on terrestrial organisms (soil macro-organisms, soil micro-organisms and terrestrial plants) with a justification based on exposure pattern in accordance to Annex IX of REACH.
Following the assessment of available data provided by the Registrant(s), any significant direct and indirect exposure to soil compartment can be excluded. Moreover, physicochemical data also indicate that this substance has a low adsorptive (log Koc =2.03) and bioaccumulative (log Kow =0.98) potential. Thus, for oxydiethylene dinitrate distribution into soil compartment and related exposure to soil organisms can be considered negligible.
The outcome of CSA indicates that there is no concern for soil organisms and therefore no toxicity testing on this endpoint needs to be required under this substance evaluation.
The evaluating MSCA considers acceptable the EPM-based screening assessment used for hazard to soil organisms, supporting the conclusions on this endpoint.

<u>Toxicity to soil macro-organisms</u>

The Registrant(s) provide a data waiving on this endpoint, with a justification based on exposure considerations according to Annex IX of REACH.

Based on the evidence presented within the registration dossier, direct and indirect exposure to soil compartment is unlikely to occur and there is no indication of concern for effects to terrestrial invertebrates.
The evaluating MSCA considers that there is no concern for soil macro-organisms and therefore no further toxicity testing on this endpoint is needed for the purpose of this substance evaluation.

Toxicity to terrestrial plants

The registration dossier does not contain data for this endpoint. In accordance with REACH Annex IX, the Registrant(s) have waived toxicity testing to terrestrial plants claiming that direct and indirect exposure to soil compartment is unlikely to occur.
The evaluating MSCA considers that there is no concern for terrestrial plants and therefore no further toxicity testing on this endpoint is necessary for the purpose of this substance evaluation.

Toxicity to soil micro-organisms

The registration dossier does not contain data for this endpoint. In accordance with REACH Annex IX, the Registrant(s) have waived toxicity testing on effects on soil micro-organisms, claiming that direct and indirect exposure to soil compartment is unlikely to occur.
The evaluating MSCA considers that there is no concern for soil micro-organisms and therefore no further toxicity testing on this endpoint is necessary for the purpose of this substance evaluation.

7.8.3. Microbiological activity in sewage treatment systems

No data available for the registered substance oxydiethylene dinitrate. The Registrant(s) provided results of a reliable test conducted on the read-across substance ethane-1,2-diyldinitrate (CAS 628-96-6), indicating an EC_{10}=13 mg/L (nominal), an EC_{20}=37 mg/L (nominal), an EC_{50}=260 mg/L (nominal) and a NOEC=10 mg/L (nominal).

Few pieces of information are reported in the IUCLID file and the CSR, therefore the evaluating MSCA evaluated the study reported in the Registration dossier of ethane-1,2-diyldinitrate. Based on similarities in molecular structure and functionality, the evaluating MSCA can support the read-across from ethane-1,2-diyl dinitrate.

7.8.4. PNEC derivation and other hazard conclusions

Table 9

PNEC DERIVATION AND OTHER HAZARD CONCLUSIONS		
Hazard assessment conclusion for the environment compartment	**Hazard conclusion**	**Remarks/Justification**
Freshwater	PNEC aqua (freshwater): 0.0323 mg/L	Assessment factor: 100 One long-term effects data for glycerol trinitrate from invertebrates is available (7d NOEC = 3.23 mg/L). Invertebrates showed the lowest L(E)C50 in the short-term tests, therefore an AF of 100 was applied
Marine water	PNEC aqua (marine waters): 0.00323 mg/L	Assessment factor: 1000 Extrapolation method: applied the standard assumption of a

		10x lower PNEC than PNECfreshwater
Intermittent releases to water	PNEC aqua (intermittent releases): 0.391 mg/L	Assessment factor: 100 Extrapolation method: based on the lowest short-term toxicity result obtained with oxydiethylene dinitrate / glycerol trinitrate from the algae trophic level (5d LC50 = 39.1 mg/L)
Sediments (freshwater)	PNEC sediment (freshwater): 0.1 mg/Kg of wet sediment	Extrapolation method: PNECs for the sediment compartment were derived using equilibrium partitioning. The approach consists of predicting the concentration in sediment based on the PNEC derived for the water compartment [PNEC aqua (freshwater): 0.0323 mg/L]
Sediments (marine water)	PNEC sediment (marine water): 0.01 mg/Kg of wet sediment	Extrapolation method: PNECs for the sediment compartment were derived using equilibrium partitioning. The approach consists of predicting the concentration in sediment based on the PNEC derived for the water compartment [PNEC aqua (freshwater): 0.00323 mg/L]
Sewage treatment plant	PNEC STP: 1 mg/L	Assessment factor: 10 Extrapolation method: One study was available for evaluating the toxicity to microorganism involved in sewage tratmant obtained with the read-across substance ethane-1,2-diyl dinitrate. The NOEC of ethane-1,2-diyl dinitrate was found to be 10 mg/L.
Soil	PNEC soil: 0.17712 mg/Kg soil dw	Assessment factor: 1 Extrapolation method: partition coefficient Soil toxicity data are not available for oxydiethylene dinitrate. Therefore, PNEC soil was derived using equilibrium partitioning method (EPM). The evaluating MSCA only notes that, according to ECHA Guidance R.10, the PNEC soil value should be referred to Kg of wet soil.

PNEC soil

In absence of any ecotoxicological data for terrestrial organisms, the PNEC soil was derived using the equilibrium partitioning method (EPM). Based on the data provided in the

registration dossier, according to ECHA Guidance R7.c the registered substance (oxydiethylene dinitrate) would fall into soil hazard category 1 and, in this context, a screening assessment based on EPM for soil risk characterization can be applied. The resulting PNEC soil value is considered valid and, in this case, the EPM-based screening assessment is sufficient and acceptable for soil risk characterization.

7.8.5. Conclusions for classification and labelling

The substance has a harmonized classification in Annex VI to the CLP Regulation as Aquatic Chronic 3 H412, based on acute toxicity data. A long-term test result is currently available for invertebrates from the read-across substance glycerol trinitrate. A NOEC of 3.23 mg/L was obtained, this result is above the limit threshold of 1 mg/L. The substance, therefore, is classified as Aquatic Chronic 3 H412, based on acute toxicity data (10 < EC50 ≤ 100 mg/L).

7.9. Human Health hazard assessment

7.9.1. Toxicokinetics

The registration dossier does not report studies on toxicokinetics but only a statement that the evaluation of toxicokinetic is based on information from three sources:
- experimental data of toxicological tests
- literature data obtained from internet
- data from toxicological databases – free and commercial

These data are not reported in the dossier so, the evaluating MSCA asked the Registrant(s) to submit the toxicokinetic study. The evaluating MSCA received a word document with a summary of conclusion reporting comments on dermal absorption without submitting the cited studies. The evaluating MSCA rejects the Registrant(s) conclusion that the substance is not absorbed through the skin.

However risk is considered controlled at workplace for systemic, long-term effect based on the fact that good work practices are in place, since as reported in the CSR the transfer is done outdoor, only tightly closed and clean drums with mixture containing of DEGDN are handled with appropriate dermal protection supported by specific activity training.

7.9.2. Acute toxicity and Corrosion/Irritation

Not relevant for this evaluation.

7.9.3. Sensitisation

Not relevant for this evaluation.

7.9.4. Repeated dose toxicity

The registration dossier contained chronic toxicity study (3-generation study published in 1978) using read-across substance (glycerol trinitrate) that was administered to rats by feeding. The study was conducted equivalent or similar to the OECD 452 with reliability 2 and was not GLP compliant.

The result indicated the incidence of neoplastic changes at the highest dose group in males (363 mg/kg/day) and females (434 mg/kg/day). These were hepatocellular carcinoma and cholangiofibrosis in the liver, and cell tumors in the testis (pressure on the tubules, aspermatogeneis) that trigger a concern for both reproductive toxicity and for carcinogenicity (see 7.9.6 and 7.9.7).
Moreover, evaluating MSCA considers the read-across for this endpoint not acceptable in the present form. Among others, the evaluating MSCA highlights the following issues:

1. not clear discussion of the overall read-across hypothesis;

2. lack of analysis of structural differences and impact of these differences on the analogues toxicological properties;
3. no endpoint specific (mode of action related) read-across justification.

The evaluating MSCA concludes that although the potential for repeated dose toxicity is not clarified, the RMM and OC for this substance provide a sufficient level of protection.

7.9.5. Mutagenicity

Oxydiethylene dinitrate was negative in Ames test with and without metabolic activation (Unpublished report, 1985) while positive result was obtained in the *in vitro* mammalian cell gene mutation assay without metabolic activation (Unpublished report 1988). For *in vitro* Chromosomal Aberration and *in vivo* genotoxicity the registrant(s) applied a read-across to glycerol trinitrate. Glycerol trinitrate was not classified as mutagen or carcinogen under CLP, based on the available data. In particular, a chronic toxicity study is available for glycerol trinitrate in rats were an increased rate of interstitial cell tumors of the testes in male rats and hepatocellular carcinomas in the male and female rats were observed and triggered a suspicion of a carcinogenic effect. Accordingly, the information provided by the Registrant(s) is not sufficient to exclude a genotoxicity potential of oxydiethylene dinitrate, contrary to what is stated in the read across conclusions. Moreover, for this endpoint the read-across approach is considered not acceptable in the present form by the evaluating MSCA (see section 7.9.4).

Therefore, to clarify the identified mutagenicity concern, a new *in vitro* MN test should be performed. However, due to highly explosive properties of the substance, performing laboratory studies with this substance would be extremely dangerous. In addition, the substance is only used in industrial stricted controlled conditions.
For these reasons the evaluating MSCA concludes that although the potential mutagenicity properties are not clarified, no new information on this endpoint needs to be requested under Substance Evaluation.

7.9.6. Carcinogenicity

No data are available for carcinogenicity or repeated dose toxicity on oxydiethylene dinitrate. The registration dossier contained a chronic toxicity study using the read-across substance glycerol trinitrate that was administered to rats by feeding. The study was conducted equivalent or similar to the OECD 452 with reliability 2 and was not GLP compliant. The result indicated the incidence of neoplastic changes at the highest dose group in males (363 mg/kg/day) and females (434 mg/kg/day). These were hepatocellular carcinoma and cholangiofibrosis in the liver, and cell tumors in the testis (pressure on the tubules, aspermatogeneis). This result paired with positive *in vitro* results in gene mutation assay triggered a suspect for carcinogene and mutation concern by evaluating MSCA. Therefore, the information provided by the Registrant(s) is not sufficient to exclude a carcinogenic potential of oxydiethylene dinitrate, contrary to what is stated in the read across conclusions. Furthermore, for this endpoint the read-across approach is considered not acceptable in the present form by the evaluating MSCA (see section 7.9.4).

However due to highly explosive properties of the substance, evaluating MSCA accepted the consideration of the Registrant(s) that is extremely dangerous to performe laboratoty tests. In addition, it should also considered that the substance is only used in strictly controlled condition. **For these reason, the evaluating MSCA concludes that although potential carcinogenic properties of the substance are not clarified, no new information on this endpoint needs to be requested under Substance Evaluation.**

7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

The registration dossier contained a reproductive toxicity study with reliability 2 and was not GLP compliant. The study was conducted using read-across substance glycerol trinitrate in rats and equivalent or similar to OECD 416, USFDA guidelines (1966).

- The result indicated severe aspermatogenesis (408 mg/kg/day), mild-moderate increases in the amounts of interstitial tissue in testes in the F2a generation that resulted in severe infertility in the F2a generation, and all litter parameters except male / female ratios were reduced in the high dose F1a litters (452 mg/kg/day).
- All litter parameters except male / female ratios were reduced in the high dose (452 mg TNG / kg / day) F1a litters.
- The food intake of the F1b dams was ~65 % that of the corresponding control dams. Their gestational product (litter size x litter weight) was ~62 % that of those control dams.

Since effects on spermatogenesis and in testes, were observed in this reproductive toxicity study, there is a concern for potential endocrine disrupting properties of the substance.
The registration dossier contained developmental toxicity study using read-across substance glycerol trinitrate in rats. The study was conducted equivalent or similar to the FDA guideline (1966) with reliability 2 and no GLP compliance.

- The result indicated the incidence of unossified and incompletely ossified hyoid bones at the highest dose group 59.3 mg/kg/day that was increased compared to the low 0.9 mg/kg/day and mid dose group 6.4 mg/kg/day and significantly increased compared to the control group.

These results triggered a concern for the reproductive toxicity. Therefore, the information provided by the Registrant(s) is not sufficient to exclude a reproductive toxicity potential of oxydiethylene dinitrate, contrary to what is stated in the read across conclusions. Furthermore, for this endpoint the read-across approach is considered not acceptable in the present form by the evaluating MSCA (see section 7.9.4). However due to highly explosive properties of the substance, performing laboratory studies to clarify these concerns would be extremely dangerous. In addition, the substance is only used in stricted controlled conditions. **For these reasons, the evaluating MSCA concludes that no new information needs to be requested under Substance Evaluation.**

7.9.8. Hazard assessment of physico-chemical properties

The substance is self classified as Expl. 1.1 H201. The evaluating MSCA agrees on the conclusion reported in the registration dossier.

7.9.9. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

The following DNELs were derived by the Registrant(s). These DNEL values are derived using the analogue substance glycerol trinitrate.
Since no exposure of the substance is expected the risk is considered controlled (see conclusions).

Table 10

CRITICAL DNELS/DMELS					
Endpoint of concern	**Type of effect**	**Critical study(ies)**	**Corrected dose descriptor(s) (e.g. NOAEL, NOAEC)**	**DNEL/ DMEL**	**Justification/ Remarks**
Inhalation Repeated dose Toxicity Workers	Systemic effects - Long-term	Most of sensitive endpoint: repeated dose toxicity (oral)	NOAEC 1.322 mg/m³	DNEL: 0.2144 mg/m³	**AF** for intraspecies differences: 5 **AF** for remaining uncertainties: 2.5 **Overall Assessment Factor:** 12.5
Dermal Repeated dose Toxicity Workers	Systemic effects - Long-term	Most of sensitive endpoint: repeated dose toxicity (oral)	NOAEL: 3.04 mg/kg bw/day	DNEL: 0.0608 mg/Kg bw/day	**AF** for interspecies differences (allometric scaling): 4 (rat) **AF** for intraspecies differences: 5 (workers) **AF** for remaining uncertainties: 2.5 **Overall Assessment** Factor: 50
Inhalation Repeated dose Toxicity General population	Systemic effects - Long-term	Most of sensitive endpoint: repeated dose toxicity (oral)	2.68 mg/m³	DNEL: 0.05287 mg/m³	**AF** for intraspecies differences: 10 (general population) **AF** for remaining uncertainties: 2.5 **Overall Assessment Factor**: 25
Dermal Repeated dose Toxicity General population	Systemic effects - Long-term	Most of sensitive endpoint: repeated dose toxicity (oral)	NOAEL: 3.04 mg/kg bw/day	DNEL: 0.0304 mg/kg bw/day	**AF** for interspecies differences (allometric scaling): 4 (rat) **AF** for intraspecies differences: 10 (general population)

					AF for remaining uncertainties: 2.5 Overall Assessment Factor: 100
Oral Repeated dose Toxicity General population	Systemic effects - Long-term		NOAEL	DNEL: 0.0304 mg/kg bw/day	**AF** for interspecies differences (allometric scaling): 4 (rat) **AF** for intraspecies differences: 10 (general population) **AF** for remaining uncertainties: 2.5 **Overall Assessment Factor**: 100

7.9.10. Conclusions of the human health hazard assessment and related classification and labelling

According to the harmonised classification the subtance has the following health hazard phrases: H201, H 300, H 330, H 373; Fatal if swallowed, in contact with skin or if inhaled. May cause damage to organs through prolonged or repeated exposure.

The identified exposure scenarios are not associated to potential risks for workes. Since the Registrant(s) based their registration dossier on data derived for the substance Glycerol trinitrate for which also uses for consumers are identified. Since exposure is considered negligible due to good work practices no further improvement of the read across is required. Moreover due to the similarity of the intrinsic properties with Glycerol trinitrate, a similar OELV could also be used for oxydiethylene dinitrate.

7.10. Assessment of endocrine disrupting (ED) properties

7.10.1. Endocrine disruption – Environment

Not relevant for this evaluation.

7.10.2. Endocrine disruption - Human health

To clarify the initial concern on potential endocrine disruptor properties a suitable reproductive toxicity study would need to be performed. However due to highly explosive properties of the substance, performing laboratoty studies would be extremely dangerous. For this reason, the evaluating MSCA concludes that although the concern is not clarified, no further information on this endpoint needs to be requested under Substance Evaluation.

7.11. PBT and VPVB assessment

Based on available information, the concern on PBT/vPvB is not clarified but the explosive nature of the substance means that further testing of PBT properties would be dangerous and not recommended.

1) Persistence

The biodegradation studies on the registered substance and results from the QSAR models indicate that the screening criteria are met but do not allow to conclude on the persistence of oxydiethylene dinitrate.
Therefore the persistence of oxydiethylene dinitrate cannot be excluded according to Annex XIII criteria of REACH.

2) Bioaccumulation

Despite the conclusions regarding aquatic bioaccumulation due to a low value of log Kow (0.98 at 25 °C, well below the triggering value of 4.5), the estimate of log Koa made with KOAWIN v1.10 (EPIWEB) on the registered substance, oxydiethylene dinitrate, that gave a value of 5.78, cannot exclude a concern for potential bioaccumulation in air-breathing organisms.

3) Toxicity

Based on ecotoxicity data set for oxydiethylene dinitrate / glycerol trinitrate that includes acute and chronic effect values for all three trophic levels, the substance does not meet the criteria to be identified as T for environmental endpoints. However, based on the harmonised classification as STOT RE 2, the T criterion is met based on the classification for human health effects.

7.12. Exposure assessment

7.12.1. Human health

7.12.1.1. Worker

Based on the available information the exposures is considered controlled.

7.12.1.2. Consumer

About the consumers, the Registrant(s) consider that the exposure assessment is not applicable as there are no consumer-related uses for the substance.

7.12.2. Environment

In the CSR, the Registrant(s) state that the environmental exposure estimations were carried out using CHESAR 2.0 (EUSES 2.1) and releases are determined primarily by tonnage and the ERC. Subsequently with taking to account realistic daily amount on site and realistic amounts released to water, air and soil.
In the introduction to the assessment of the CSR, the Registrant(s) comments that the waste water containing oxydiethylene dinitrate is cleaned in on-site waste water treatment facility (physical/chemical/biological treatment), that ensure no emission of oxydiethylene dinitrate to the environment by waste water path.
Moreover, the Registrant(s) affirm that the Exposure of man via environment is unlikely. There are no releases to waste water and contamination of soil is not expected. Releases to air are probably subject to conditions of presumed photolysis in air.
The CSR describes only industrial use in formulation and preparation of ammunition. No end use in explosives scenario is considered. It is reasonable to assume that the releases due to this scenario are negligible since the substance is converted into carbon dioxide, nitric oxides and water. In addition no default ERCs for this scenario are foreseen in the Guidance on information requirements and Chemical Safety Assessment.

7.13. Risk characterisation

The Registrant(s) conclude that the risk is controlled for humans (workers and man via the environment). The risk is also controlled in aquatic and terrestrial compartments. For the air, the Registrant(s) state that the risk characterization is not need, and no hazard identified. Based on availale information, the evaluating MSCA can support the Registrant(s)' conclusions.

7.14. References

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7.15. Abbreviations

CAS Chemical abstracts service
C&L Classification and labelling
CLP Classification, labelling and packaging (Regulation (EC) No 1272/2008)
CSR Chemical Safety Report
MSCA Member State Competent Authority
OC Operational Condition
OECD Organisation for Economic Co-operation and Development
OELV Occupational Exposure Limit Values
RMM Risk Management Measure
PBT Persistent, Bioaccumulative, Toxic
vPvB Very Persistent and very Bioaccumulative