Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on

2,4-dinitrotoluene in articles

ECHA/RAC/RES-O-0000007105-81-01/F

ECHA/SEAC/RES-O-0000007148-71-01/F

EC Number	CAS Number
204-450-0	121-14-2

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Summary

2,4-dinitrotoluene (2,4-DNT) is classified under Regulation (EC) No 1272/2008 (CLP) as a carcinogen category 1B, H350 (may cause cancer)[1] and was therefore included in the candidate list for authorisation (13/01/2010; ED/68/2009[2]) and into Annex XIV of REACH (Commission Regulation (EU) No 143/2011) on the basis of Art 57(a) of REACH, with a sunset date of 21/08/2015. Following an assessment of the available evidence in accordance with Article 69(2) of the REACH Regulation, ECHA considers that there are uses of 2,4-DNT which may lead to a non-adequately controlled risk from the presence of the substance in articles. This Annex XV restriction proposal addresses those risks in articles not already regulated. Whilst there is no information available on current manufacture, import or export of 2,4-DNT in the EU, and ECHA has received no registrations for the substance, the restriction would also prevent potential future uses of the substance in articles.

2,4-DNT is an isomer of the multi-constituent substance DNT (EC: 246-836-1). Two of the isomers of DNT, 2,4-DNT and 2,6-DNT, make up 95 % of DNT whereas four other isomers (2,3-, 2,5-, 3,4-, and 3,5-DNT) account for the remaining 5 %. Currently, there are no registrations of 2,4-DNT but there are two active REACH registrations for DNT (one for 1-10 tonnes/year and the other as an intermediate). Before 2010, technical grade DNT (commonly having concentrations of 75-80 % of 2,4-DNT) was produced at 5-6 sites in the EU for the production of toluene diisocyanate. DNT containing a 50-55 % concentration of 2,4-DNT has been imported for use as a binding agent in the non-ferrous metal industry and in propellants. These uses have been in the range of 1-10 t/year with technical grade DNT reportedly used before 2010. Other DNT isomers and DNT itself, are not specifically targeted by this restriction initiated under Article 69(2) of REACH, but they may also be in scope if included in articles, when 2,4-DNT is present above a concentration limit of 0.1 % and where the presence of 2,4-DNT is a result of using DNT with varying isomer content ratios.

Current or previous uses of 2,4-DNT have been identified in various articles including in refractories, in automotive airbags, in seat belt pre-tensioners, in plastic bottles used in industrial settings for sample taking purposes, as propellants for military and civil small-arms ammunitions, as gelatinising-plasticising agent in explosive compositions, and as a plasticising and waterproofing agent for propellants in gun powders. The latter two uses are considered mixtures as they are not produced as an integral part of an article[3]. Two notifications of a substance in articles (SiA) have been made under Article 7(2) of REACH for 2,4-DNT; for the use as plasticiser in plastic sample bottles used at industrial settings, for which the notifying entity has now ceased, and for the use in propellants for military ammunition articles. Furthermore, the US Environmental Protection Agency lists possible uses of 2,4-DNT in sports equipment and in outdoor toys such as sandboxes. No details of the import, use or manufacture of these articles are available, however.

A search of the SCIP database[4] for 2,4-DNT indicated that there are articles in the EU containing the substance used in vehicles, ceramic articles and electronic devices. This information confirms there are additional articles (probably imported) that contain the

[1] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/6510.
[2] Inclusion of substances of very high concern in the candidate list, Decision by the Executive Director
[3] See *Guidance on requirements for substances in articles* (ECHA 2017).
[4] In accordance with the Waste Framework Directive, companies supplying articles containing substances on the Candidate List in a concentration above 0.1 % w/w on the EU market shall submit information on these articles to ECHA, from 5 January 2021 onwards. This information is then included in the SCIP database. An extract of the Dossier Submitter's SCIP query is provided in a confidential annex.

substance. The use in seat belt-pretensioners and ammunition has been confirmed during the consultation on the Annex XV restriction dossier.

2,4-DNT can be released from articles into water, air, and soil at places where they are produced or used. This restriction proposal targets consumer and professional uses in articles where release and exposure of 2,4-DNT cannot be excluded and risk management measures are difficult to implement. For example, 2,4-DNT is applied in plastic sampling bottles used in industrial settings for sample taking where the substance acts as a softener. Possibility of migration and worker exposure of 2,4-DNT from these bottles cannot be excluded. Traces of 2,4-DNT may also be found in refractory products where, again, exposure from the use of the articles cannot excluded.

Consumer exposure may occur from the use of civilian small arms ammunition such as hunting and sports shooting, if the ammunition propellant contains 2,4-DNT. Shooting of the firearm does not consume all 2,4-DNT used in the ammunition and exposure via inhalation or dermally may occur. Two other uses with exposure potential are in seat belt pre-tensioners, where an explosive charge causes the gas generator to produce a volume of gas and thus pressure, which then acts on a mechanical linkage to pull the seat belt; and in air bags, where deployment releases gas in a similar manner as in pre-tensioners. For uses of 2,4-DNT in vehicle safety systems, groups at risk of exposure include, in addition to the driver, e.g. car repair technicians or in case of an accident, the rescue forces. In these uses, inhalation and dermal exposure may occur.

Studies of DNT carcinogenicity have been conducted in ammunition production facilities, in the copper mining industry and at ammunitions production facilities. These studies found an association between cumulative DNT exposure and renal cell cancer. Particularly an association between dermal, but also inhalation, exposure to DNT and renal cancer has been established for miners. Exposure relates predominantly to the handling (and possible inhalation of residuals of) DNT-containing explosive sticks.

2,4-DNT is considered as non-threshold substance for which no DNEL can be derived. Therefore, ECHA as the Dossier Submitter is of the view that 2,4-DNT incorporated in articles poses a risk to human health that is not adequately controlled. The use of 2,4-DNT in the production of articles in the EU is subject to authorisation requirements under Title VII of REACH. Authorisation requirements do not apply to imported articles though and it is thus likely that articles containing 2,4-DNT are produced outside the Union and subsequently imported in the EU, causing a risk to human health that needs to be addressed.

As part of this restriction proposal, an analysis of risk management options (RMOs) was conducted to identify the most appropriate measure to address these risks. The Dossier Submitter concluded that action is required to reduce risks for consumers and professional and industrial workers on a Union-wide level and that the proposed restriction is the most appropriate measure. The restriction is assumed to impose very low costs to reduce a potential risk; given the information at hand, it is assumed that the measure is proportionate to the risk. Alternatives to 2,4-DNT exist for the identified uses. There is no known EU production of articles using the substance, except for the production of military ammunition. For other uses, there is no need to transition to alternatives or to deplete stocks. If there are any imported articles, time may be needed for importers to transition to alternative articles not containing

2,4-DNT. It is assumed that 12 months would be a sufficient transition time. For the restriction it is proposed to use the same concentration limit as in the toys legislation.[5]

The scope of the proposed restriction covers articles placed on the EU market that contain 2,4-DNT (seat belt tensioners, plastic sample bottles, ammunition, refractory materials, and others). Specific derogations are proposed.

Standardised laboratory methods for measuring 2,4-DNT in articles (and environmental samples) do exist, suggesting that the restriction is practical and monitorable. The presence of articles on the market containing 2,4-DNT could be monitored using databases or applications such as the ones that were used as sources for the preparation of this Annex XV report. The restriction is targeted to the effects or exposures that are of most concern, e.g. those from consumer and professional uses.

As the restriction is assumed to impose very low costs to reduce a potential risk, and given the information at hand, the Dossier Submitter considers that the measure is proportionate to the risk.

A call for evidence was held 27/1/21 to 10/3/21 (https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/27201/term); two comments were received, one giving further information on occupational exposure to 2,4-DNT (from production and handling of explosives) between 1990 and 2021. No additional information on uses or challenging the assumptions made in the restriction proposal was received.

[5] Directive 2009/48/EC on the safety of toys.

Proposed restriction

Brief title: Restriction in articles for consumer and professional uses.

Table 1: proposed restriction

Column 1	**Column 2**
2,4-Dinitrotoluene EC Number: 204-450-0 CAS Number: 121-14-2	1. Shall not be placed on the market, or used, as a substance in articles for supply to the general public or to professional workers in concentrations $\geq$ 0.1 % weight by weight. 2. Paragraph 1 shall not apply to a substance in articles placed on the market or used in: a. Explosives, b. Ammunition intended for use, in accordance with national law, by the armed forces or the police. 3. Paragraph 1 shall not apply to a use of the substance in articles regulated by: a. Directive 2009/48/EC on the safety of toys, b. Regulation (EU) 2017/745 on medical devices, c. Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. 4. Use and placing on the market of articles already in use in the Union before {IEF} containing 2,4 DNT shall be allowed. 5. For the purposes of this entry: a. professional uses mean use by workers outside industrial installations. b. explosives mean the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations, with the exception of pyrotechnic articles. Pyrotechnic articles include ammunition. 6. The restriction should enter into force after {date 12 months after entry into force}.

SEAC box

In addition to supporting the Dossier Submitter’s proposal in Table 1, SEAC concluded that a 36-month derogation period for uses of 2,4-DNT in Micro Gas Generators (MGGs) and spare parts in the car industry is justified based on the comments received in the stakeholder consultation on the SEAC draft opinion.

1. Problem Identification

1.1 Background

2,4-dinitrotoluene (2,4-DNT) is classified under Regulation (EC) No 1272/2008 (CLP) as a carcinogen category 1B, H350 (may cause cancer) and was therefore included in the candidate list for authorisation (13/01/2010; ED/68/2009[6]). It was included into Annex XIV of REACH (Commission Regulation (EU) No 143/2011) on the basis of Art 57(a) of REACH, with a sunset date of 21/08/2015. No applications were received for the use of 2,4-DNT as a substance, substance in a mixture or incorporation of the substance into articles. The supply of 2,4-DNT to the general public is currently restricted as a substance and in a mixture containing ≥ 0.1 % DNT (Annex XVII of REACH, entry 28 and appendix 2).

2,4-DNT is available commercially as a purified isomer or as a component of technical grade dinitrotoluene (DNT).[7] Technical grade DNT is a mixture of isomers (approximately 80 % of 2,4-DNT and 20 % of 2,6-DNT) which is primarily used as a non-isolated chemical intermediate in the production of toluene diisocyanate (TDI). This in turn is used to make flexible polyurethane (PU) foams. The use of 2,4-DNT as a non-isolated intermediate is exempted from REACH.

Current or previous uses of 2,4-DNT have been identified in various articles including as a temperature specific cross-linking agent for refractories, in automotive airbags, in seat belt pre-tensioners, in plastic bottles used in industrial settings for sample taking purposes, as propellants for military ammunitions, as gelatinising-plasticising agent in explosive compositions, and as a plasticising and waterproofing agent for propellants in gun powders. However, only two notifications of a substance in articles (SiA) have been made under Article 7(2) for 2,4-DNT; one for the use as plasticiser in plastic sample bottles used at industrial settings, for which the notifying entity has now ceased, and one for the use in propellants for military ammunition articles.

2,4-DNT is a non-threshold carcinogen. Annex I Section 6.5 of REACH requires for human effects for which it was not possible to determine a DNEL, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out. In addition, RAC (2012) has taken a position in relation to applications for authorisations that for such substances adequate control is not achievable, neither for the use of that substance on its own nor in a mixture or the incorporation of the substance into an article.[8] Therefore, only a qualitative assessment is carried out for the substance.

According to ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012), a qualitative approach has to be chosen when no reliable dose descriptor (without identified thresholds) can be set for a given endpoint. The purpose of the qualitative risk assessment is to assess 'the likelihood that effects are avoided when implementing the exposure scenario…' as expressed in REACH Annex 1, Section 6.5. As these are non-threshold substances it cannot be excluded that risks to consumers can occur. In addition, traditional operational conditions (OC) and risk managements measures (RMM),

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[6] Inclusion of substances of very high concern in the candidate list, Decision by the Executive Director of ECHA.
[7] EC: 246-836-1, CAS: 25321-14-6.
[8] https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf

such as level of containment and use of personal protective equipment, are not implementable by consumers and are also often difficult to implement by professional users. The only way to manage the risk in the case of articles where there is exposure to consumers and professional users is to limit the presence of unwanted substances.

The Dossier Submitter takes note of the EU General Court judgment of 7 March 2019 in Case T-837/16, Sweden v. Commission and the Commission's document from 27 May 2020 on the assessment of alternatives: Suitable alternative available in general & requirement for a substitution plan[9] in relation to applications for authorisation. The Commission document states that "In other words, the substitution plan creates an obligation to set out and implement the actions and the timetable towards substitution of the hazardous substance". The Dossier Submitter recognises the aim of REACH to substitute the SVHC substance on the EU market, including the SVHCs in articles, where this is technically and economically viable.

1.2 Manufacture and uses

1.2.1 Manufacture and import (brief overview)

Before 2010, DNT was manufactured at 5 or 6 sites in the EU (Technical report, 2010) where the substance was exclusively used in the manufacture of toluene diisocyanate (TDI). Most of the sites manufactured 'technical grade' DNT in quantities between 540 000 and 810 000 tonnes per year, which is equivalent to 405 000 and 648 000 tonnes of 2,4-DNT per year (assuming common concentrations of 75-80 % of 2,4-DNT in technical DNT).

One EU company has been reported as importing 50-55 % 2,4-DNT in the range 100-1 000 tonnes per year for use as a binding agent in the non-ferrous metal industry. Import of propellants that contain technical grade DNT of an unknown 2,4-DNT content had also been reported in the range 1-10 t/year (ECHA, 2010). Currently, there are no registrations of 2,4-DNT but there are 2 registrations for DNT (one for 1-10 tonnes/year and the other as an intermediate) with a life cycle description of formulation into mixture used in explosives.

There is no current manufacture or import of 2,4-DNT in the EU as ECHA has not received any authorisation for applications for this substance and has no information if there is manufacture for the uses exempted from authorisation or for export. However, a response in the consultation (#3541) indicated there are several defence exemptions that allow for the continued use of 2,4-DNT in the production of propellants which are later used in the production of (military) ammunition. This would mean no authorisation applications for these exempted uses were required.

1.2.2 Uses

Use of the substance or mixture (brief overview)

2,4-DNT is mostly used as chemical intermediate in the production of toluene diisocyanate (4-methyl-m-phenylenediisocyanate). It is hydrogenated to yield toluenediamine (TDA) and this diamine is reacted with phosgene to yield toluenediisocyanate (TDI), which is used to make flexible polyurethane foams. Other,

[9] https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf

minor uses as an intermediate include the use in the production of dyes and dyestuffs and rubber chemicals.

Legacy uses as an intermediate in the synthesis of dyes have been described in the literature. 95 % 2,4-DNT ('pure' DNT) was used in the past in the manufacture of other dyes (Technical report, 2010). The available information suggests that there is at present no use of 2,4-DNT in dye manufacturing (ECHA, 2010).

2,4-DNT can also be used in smokeless propellants for explosives and ammunitions where it acts as a stabiliser, flash and temperature suppressor (ECHA, 2010). The role of DNT has also been described as a plasticiser[10] and as a waterproofing agent (Technical report, 2010). 2,4-DNT can also be the main energetic compound together with nitroglycerine in some propellants and the propellants may then contain 2,4-DNT in concentrations of +/- 10 % (US Department of Defense, 1973).

According to the Technical report (2010), DNT was still used as an additive in the manufacture of explosives (dynamite) in 2010 as there was one EU based company which still supplied 'pure' DNT and DNT 65/50 to EU and non-EU customers for the manufacture of explosives. The amounts of DNT used in or supplied to the explosives sector were however unclear. DNT (50/55) has been used also in the non-ferrous metals industry as a temperature-specific cross-linking agent for refractories in amounts of less than 1 000 t/year (Technical report, 2010).

The 'pure DNT' is also used in applications for which limited information is available, such as a fuel additive (Technical report, 2010). DNT 65/50 may also be used as a component of explosive materials (Technical report, 2010).

Recycling of trinitrotoluene (TNT) ammunition may also lead to DNT isomers present in the product as an impurity (Technical report, 2010).

Uses of substances in articles

As mentioned, there are currently only two SiA notifications made under Article 7(2) for 2,4-DNT; for the presence as plasticiser in plastic sample bottles used at industrial settings and for the presence in propellants for military ammunition articles. However, it should be noted that notification is not required if a substance is present in the specific articles in quantities less than one tonne per producer or importer per year. Hence there may be more (low-quantity) uses in articles.

The sections below cover other potential uses of 2,4-DNT in articles. However as these have not been notified to ECHA in accordance with Article 7(2), the Dossier Submitter assumes that these articles i) are currently not used in the EU, ii) have not been notified by any importers, or iii) their quantities are lower than one tonne per year in articles.

The Dossier Submitter further notes that there have been no Safety Gate notifications for 2,4-DNT.[11]

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[10] Energetic material pyrotechnic compositions often employ plasticisers to improve physical properties of the propellant binder or of the overall propellant, to provide a secondary fuel, and ideally, to improve specific energy yield (e.g. specific impulse, energy yield per gram of propellant, or similar indices) of the propellant. An energetic plasticiser improves the physical properties of an energetic material while also increasing its specific energy yield.
[11] Reviewed on 15 December 2019 for 2,4-DNT, DNT and technical DNT.

Occupational uses

Ammunition

Propellants are usually regarded as substances/mixtures within the context of the REACH Regulation and thus as such are not within the scope of this report. However, when they are as an integral part of an article (e.g. within an ammunition or artillery shell), they are regarded as part of the article. The ammunition cartridge containing the propellant is designed to launch a projectile and the shape, surface and design of such ammunition cartridges therefore determine their function to a greater degree than does its chemical composition.[12]

2,4-DNT is used mostly in single-based or double-based solid propellants. Single-based powders contain nitrocellulose as the sole energetic material. Jenkins and Vogel (2014) did not list 2,4-DNT as an ingredient for double base propellants, and it seems that even if it can be found from this propellant type, it is not as often included in the principal ingredients as in single base propellants. The review by Pichtel (2012) lists 2,4-DNT in the composition of single and double based propellants.

2,4-DNT can also be found in variety of concentrations in small arms ammunitions such as rifle and pistol projectiles. For some uses 2,4-DNT can still be found in the final product. One identified use of 2,4-DNT is in propellants for ammunition and explosives. Propellants may be found as an integral part of an article in a wide range of explosive articles including (but not limited to):

- *Articles from recycled trinitrotoluene (TNT) ammunition*
- *As an impurity in TNT containing explosive articles and ammunition*
- *Other explosive articles*
- *Small arms ammunition cartridges*
- *Artillery ammunition*

In addition, manufacturing or recycling of TNT ammunition may lead to DNT isomers being present in the product as an impurity. It is unknown if such recycled material is incorporated into explosive articles.[13]

Consultation response #3541 indicated that there are several defence exemptions for the continued use of 2,4-DNT in the production of propellants which are later used in the production of (military) ammunition.

Refractory products

2,4-DNT has had applications in refractory products where it is used as a temperature specific cross-linking agent for refractories. It is possible that some of these applications fall within the definition of an article under the REACH regulation. Such products where

[12] ECHA QA ID No 1059: https://echa.europa.eu/support/qas-support/qas
[13] As defined by Article 3(3) of REACH, an article "means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

DNT is transformed to another substance with possibility of traces of DNT in the final product:[14]

- *fired carbon cathodes – primary aluminium smelting*
- *fired carbon blocks – primary aluminium smelting*
- *ferro-alloy manufacture as furnace linings, inorganic chemical vessel linings e.g. phosphoric acid*
- *carbon ramming pastes – primary aluminium smelting, blast furnace linings, ferro-alloy furnace linings*
- *grouts – blast furnace linings, ferro-alloy furnace linings*
- *tap hole clays – ferro-alloy furnace linings*
- *bricks*

The production of these refractory products is within the scope of the authorisation, if 2,4-DNT is used in treating of these articles, as this is not regarded as an intermediate use according to the Commission and ECHA. The interpretation has earlier been challenged by the industry in relation to other substance and the industry has therefore not applied authorisation for this specific use. ECHA is not assessing this use in this article 69(2) report as this should be covered by the authorisation.

<u>Plastic containers</u>

The notifying entity for plastic containers has ceased the use but it cannot be excluded that other companies are importing and using these containers, even though a notification is required if the tonnage per importer per year is above 1 t.

Consumer uses

<u>Ammunition</u>

In addition to occupational uses of ammunition, civilian small arms uses such as hunting and sport shooting may apply 2,4-DNT containing cartridges.

<u>Automotive airbags and seat belt pre-tensioners</u>

Use of 2,4-DNT in automotive airbags has been cited and some current uses in seat belt pre-tensioners have been indicated by vehicle manufacturers. In these automotive safety applications, 2,4-DNT is used in the pyrotechnic charge component that fires to pull the seat belt in to pull the passenger away from the airbag while it is deployed with a similar pyrotechnic application.

Some vehicle safety systems such as air bags have been indicated to use 2,4-DNT (EU RAR, 2008). Also, seat belt pre-tensioners have been suggested as a possible use. According to the Technical report (2010), vehicles with 2,4-DNT containing parts are not

[14] The possibility for products to have traces of 2,4-DNT was indicated in the consultation for EU RAR 2008.

placed on the EU market. However, some vehicle manufacturers do indicate to have 2,4-DNT in some of their models' seat belts, likely referring to the pre-tensioners.[15,16]

Response #3526 in the consultation on the Annex XV restriction report indicated that 2,4-DNT is used in seatbelt pretensioners at a maximum amount of 80 mg. is the Dossier Submitter assumes that these are imported into the EU as no application for the use of incorporating 2,4-DNT in articles has been submitted.

Other potential consumer uses

The presence of 2,4-DNT in refractory products is considered an uncertainty. Some products can be considered as articles (such as bricks), but no new information on the use of 2,4-DNT in these articles was discovered during the work on this restriction proposal report. In addition, the US EPA Chemical and Products Database (CPDat) indicates there are other uses of 2,4-DNT that have not been previously identified in EU articles. It is not clear if relevant articles in Table 2 are imported into the EU (potential consumer articles are highlighted in red).

Table 2: List of 2,4-DNT uses in substances, products and articles according to US EPA Chemical and Products Database.

Category	Category Description	Categorization Type
Appliance, heating, lawn garden	Products used outside the home (includes outdoor toys such as sandboxes, canopies and shelters, garden statues, outdoor lighting and seating, outdoor power equipment, etc.)	CPCat Cassette
Consumer use, detected	Chemicals detected in substances or products (note that these chemicals may be absent from an 'ingredient list' for the product and thus unexpected, but have been detected in product testing studies)	CPCat Cassette
Explosives	Explosives and pyrotechnics	CPCat Cassette
Heating, fire, lawn garden	Products used outside the home (includes outdoor toys such as sandboxes, canopies and shelters, garden statues, outdoor lighting and seating, outdoor power equipment, etc.)	CPCat Cassette
Industrial manufacturing		CPCat Cassette
Manufacturing, chemical	General term used only when the only information known from the source is 'chemical,' typically related to manufacturing of chemicals, or laboratory chemicals	CPCat Cassette

[15] Pursuant to REACH article 33(2) a supplier of a product which include any article which contains more than 0.1 % by weight of Candidate List Substance to provide their customers with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. See e.g. Toyota Aygo: https://www.toyota-europe.com/world-of-toyota/feel/environment/just-better/chemical-management

[16] https://www.ford.co.uk/content/dam/guxeu/uk/useful-information/reach/Art-33-1-Information-Example-U502-Explorer.pdf

Personal care, cosmetics, prohibited ASEAN	Chemicals prohibited from use (i.e. completely banned) in the ASEAN countries (Association of Southeast Asian Nations)	CPCat Cassette
Sports equipment	Sporting equipment (e.g. soccer balls, basketball rims, fishing rods, tents, boating accessories, fitness equipment, boats/boating equipment, etc)	CPCat Cassette

Source: EPA Chemical and Products Database (CPDat)

URL: https://comptox.epa.gov/dashboard/DTXSID0020529#exposure

In addition, a search of the SCIP database for 2,4-DNT indicated that the substance is found in several article types: vehicles, ceramic articles and electronic devices. This information confirms that there are additional articles (probably imported) that contain the substance. The results of the SCIP query are included as a confidential annex to this report. The Dossier Submitter will assume the SCIP entries relate to actual uses unless information is received otherwise.

Conclusion

Overall, the Dossier Submitter considers that, whilst there is some uncertainty about the pervasiveness of actual uses in and exposures from articles, it is likely that exposure to 2,4-DNT via consumer and professional articles does occur in the EU.

Uses advised against by the registrants

No registrations have been submitted to ECHA.

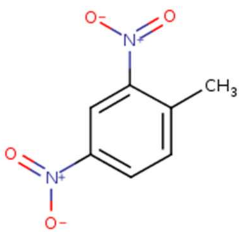
2. Hazard, exposure and risk

2.1 Identity of the substance and physical and chemical properties

2.1.1 Identity of the substance(s) and physical and chemical properties

Name and other identifiers of the substance(s)

Chemical name:	2,4-Dinitrotoluene
EC Number:	204-450-0
CAS Number:	121-14-2
IUPAC Name:	1-methyl-2, 4-dinitrobenzene
Molecular Formula:	C7H6N2O4
Structural Formula:	



Molecular Weight: 182.14

Typical proportion %: ≥99 %

Real proportion (range) in %: No data available

2.1.2 Physicochemical properties of 2,4-Dinitrotoluene

Table 3 provides a summary of the physicochemical properties of 2,4-DNT.

Table 3: Physicochemical properties of 2,4-Dinitrotoluene

Property	Value	Reference
Physical state at 20 ºC and 101.3 KPa	Solid	EU RAR (2008)
Melting / freezing point	69.9 ºC	EU RAR (2008)
Boiling point	319.5 ºC	EU RAR (2008)
Vapour pressure	7.9·10-3 Pa at 20 ºC	EU RAR (2008)
Water solubility	166 mg/l at room temperature	EU RAR (2008)
Partition coefficient octanol/water (log value)	1.98	EU RAR (2008)
Dissociation constant	Not available	

2.2 Justification for grouping

2,4-DNT is an isomer of the multi-constituent substance DNT (EC: 246-836-1)[17] that has altogether six isomers: 2,4- and 2,6-DNT are the two major forms and 2,3-DNT, 2,5-DNT, 3,4-DNT and 3,5-DNT are minor isomers (ATSDR, 2016). 2,6-DNT (EC: 210-106-0) is classified as Carc. 1B (may cause cancer), Acute Tox. 3, Muta. 2, STOT RE 2, Aquatic Chronic 3 and Repr. 2. 2,6-DNT is often found in smaller amounts and as impurity in 2,4-DNT containing articles as even "pure" 2,4-DNT has five percent of other DNT isomers, mostly 2,6-DNT. However, if the articles containing 2,6-DNT contain > 0.1 % of 2,4-DNT then they would also be included in the restriction. This restriction proposal however only covers the use of 2,4-DNT in articles.

[17] See DNT registrations: https://echa.europa.eu/information-on-chemicals/registered-substances/-/disreg/substance/100.042.564

2.3 Classification and labelling

2.3.1 Regulation (EC) No 1272/2008 (CLP Regulation)

The classification and labelling of 2,4-DNT is given in Table 4.

Table 4: Entries in Annex VI of CLP for relevant substances

Index #	International Chemical Identification	EC #	Classification	Specific Conc. Limits, M-factors	Notes	ATP inserted/ updated
609-007-00-9	2,4-dinitrotoluene;	204-450-0	Acute Tox. 3 H301, H311, H331; Muta. 2 H341; Carc. 1B H350; STOT RE 2 H373; Aquatic Acute 1 H400; Aquatic Chronic 1 H410; Repr. 2 H361f.	-	-	CLP00/ATP 01

2.3.2 Self-classification

There have been 137 notifications to the C&L inventory for 2,4-DNT, some of them indicating the following additional endpoints: Carc. 2 H351, STOT SE 1 H370, STOT RE 1 H372.

2.4 Human health assessment

2,4-DNT is classified as carcinogenic category 1B substance, which was the basis for its identification as Substance of Very High Concern (SVHC). The EU RAR (2008) identified carcinogenicity and mutagenicity as the key concern. As the substance is mutagenic, it is assumed that the Mode of Action for carcinogenesis is non-threshold. Therefore, it is not possible to identify a clear exposure threshold below which there would be no risk of cancer in humans. The EU RAR (2008) highlighted that 2,4-DNT activity was in the medium potency range (1 mg/kg bw/day < T25 = 14.39 mg/kg bw/day < 100 mg/kg bw/day). Furthermore, the RAR concluded that 2,4-DNT is an in vivo mutagen and thus genotoxicity is likely to be the underlying mechanism or an important contributory factor of carcinogenicity.

Epidemiological studies of DNT carcinogenicity have been conducted in relatively small groups of workers in ammunition production facilities, copper mining industry and at ammunitions production facilities (Stayner et al., 1993, Brüning et al., 1999, Brüning, 2001, Brüning et al., 2002). As summarised in Seidler et al. (2014), the epidemiological and animal studies point to possible aetiological role of DNT exposure on renal and urothelial cancer. Seidler et al. (2014) reviewed the aforementioned studies of Brüning, reporting increased renal cell carcinoma risk and toxic nephropathy with proximal tubular damage in small number of DNT-exposed underground miners. Seidler et al. (2014) found an association between cumulative DNT exposure and renal cell cancer in a cohort of 16 441 male workers in the Mansfield copper mining industry. The study found particularly dermal but also inhalation DNT exposure association with renal cancer among miners in different roles in relation to DNT containing explosive stick handling and possible inhalation exposure. They argue that also the findings of Brüning et al. (1999) of dose-dependent increase in tubular damage due DNT exposure indicates a plausible pathological pathway from exposure to carcinogenesis.

2.5 Humans via the environment

It has been reported that, as a result of its moderate solubility, DNT can be transferred to plants via root uptake from soil and is expected to accumulate readily in plant materials (EPA, 2008). 2,4-DNT and its metabolites have been extracted from plant material in studies where different plant species have been exposed to 2,4-DNT. DNT's bioavailability and toxicity to plants are greatly altered by soil properties. Studies have found that the toxicity of 2,4- and 2,6-DNT for various plant species is significantly and inversely correlated with soil organic matter content (Rocheleau et al., 2010).

2.6 Exposure Assessment

For this restriction report only the uses of 2,4-DNT in articles are considered. 2,4-DNT in articles can be present in propellants used in artillery and small arms ammunition, plastic containers, in vehicle safety systems and possibly in TNT ammunition due to impurity or recycling of 2,4-DNT containing ammunition. Furthermore, traces of 2,4-DNT can possibly be found in refractory products.

Other potential uses in articles have been indicated. An interrogation of the SCIP database for 2,4-DNT indicate that the substance is found in several article types: vehicles, ceramic articles and electronic devices. This information confirms there are additional articles (probably imported articles) that contain the substance. The results are included as a confidential annex to this report.

Below, the Dossier Submitter presents a generic assessment of both professional and consumer exposure to 2,4-DNT used in relevant articles.

2.6.1 Worker exposure assessment

Plastic containers

In 2010, ECHA received a SiA notification reporting a use of 2,4-DNT in plastic sampling bottles as a softener. The bottles were used in industrial workplaces only. The use is no longer active for the notifying entity[18] but it is not clear if such containers or other plastic articles possibly containing 2,4-DNT are used elsewhere in the EU by professional users for example. Therefore, as an illustrative example, an exposure scenario is given to indicate the potential exposure if these containers were used by professional workers.

No information was received that would indicate whether, and to which extent, 2,4-DNT is released from plastic containers; neither is there information on exposure to 2,4-DNT from plastics available.

Although exposure measurements or estimation are not available for 2,4-DNT in plastics articles, it is possible to elaborate qualitative argumentation to estimate the exposure potential for this particular use. First, plasticisers/softener are used in relatively high concentration in plastic matrix to deliver their function; up to 35 % of plasticisers in soft PVC have been reported and measured[19].

Second, plasticisers show a relatively high diffusivity in (soft) plastic material like PVC. In fact, the equation proposed under Food Contact Material (JRC, 2015) to get a first estimation of the diffusion coefficient of plasticisers in soft PVC gives rise to the highest values of the diffusion for a given value of temperature and molecular weight if compared to other combination of additives and plastic materials. Moreover, diffusion is inversely proportional to the molecular weight (smaller molecules diffuse easier in the plastic matrix3). 2,4-DNT has a relatively low molecular weight (182 g/mol), lower than e.g. phthalates used as plasticisers (DEHP, BBP, DBP, DIBP) that have been reported to have high exposure potential for dermal and oral route.

Third, there is also an indication from the ECHA PLASI Project that the partitioning from plastic material surface and contact media (water, saliva, skin) is regulated mainly by solubility (S) and/or octanol water partition coefficient (Kow)[20]. In particular, chemicals with low Kow have higher potential to be transferred from the plastic surface to the contact medium, as shown in different studies[21,22]. 2,4-DNT has a relatively low Kow (Log Kow = 1.98) suggesting a tendency for the substance to migrate to water, saliva or skin once it has reached the plastic surface. Other plasticisers like DEHP, BBP, DBP, DIBP with much higher log Kow, ranging from 4 to 6, have been reported to have high potential for exposure

[18] Communication via email in 2020.

[19] Specific default (maximum) concentrations of additives (per technical function) in plastic articles are proposed by European Plastics Converters Association (EuPC) in their Plastic Industries Supply Chain Exposure Scenario Tool: https://www.polymercomplyeurope.eu/pce-services/pestool-service and www.pestool.eu.

[20] See the ECHA PLASI (Plastic additives initiative) Project and https://echa.europa.eu/documents/10162/13630/plastic_additives_supplementary_en.pdf/79bea2d6-8e45-f38c-a318-7d7e812890a1

[21] Correlation of partition coefficients KPolymer/Food and KOctanol/Water for potential migrants in food contact polymers, Asako Ozaki, Anita Gruner, Angela Störmer, Rainer Brandsch, Roland Franz, Poster presentation at the 4th in-ternational Symposium on Food Packaging, 19-21 November 2008, Prague

[22] Screening-level models to estimate partition ratios of organic chemicals between polymeric materials, air and water (Reppas-Chrysovitsinos et al., 2016)

Therefore, the exposure potential of 2,4-DNT as softener / plasticiser in plastic articles and more in general as additive in any plastic material can be predicted to be high, since, based on its physicochemical properties, it is assumed to diffuse easily in the plastic matrix and partition from surface to contact medium (water, saliva or skin).

2,4-DNT in TNT and other explosives

ECHA has not received any applications for authorisation on 2,4-DNT, thus it is assumed that all uses of 2,4-DNT in explosive articles, if any, are related to imports.

2,4-DNT can be found in TNT as an impurity (from the use of DNT as an intermediate in the manufacture of TNT) or as intentionally added (as a plasticiser), however the concentrations are considered to be low in comparison to applications in propellants (see Table 5). 2,4-DNT may also be present in TNT which is recovered from old explosives and ammunition (Technical report, 2010).

During the consultation for the Technical report (2010) one company was reported to have used DNT in small concentrations in Octol but discontinued the use already in 1990s. Octol is a melt-castable high explosive mixture consisting of HMX[23] and TNT in different weight proportions where DNT functioned as melting/solidification moderator (Technical report, 2010). During the consultation it was further confirmed that DNT may be found in use as an intentional component in explosives and past use in dynamite was also reported (Technical report, 2010).

In 2010, one company still supplied DNT 95 and DNT 65/50 to EU and non-EU customers for the manufacture of explosives. In 2010 the general amounts of DNT 95 sold in the EU for explosives/ammunition was in the 100-1,000 t/y range and for DNT 65/50, EU sales for the manufacture of explosives were in the 10-100 t/y range (Technical report, 2010).

The information gathered for the Technical report (2010) concludes that DNT can be present as an impurity in TNT but is often the form of the DNT isomer mixture, rather than 2,4-DNT only.

TNT and other explosives are only relevant for this screening report if they are incorporated in articles as per definition of REACH.

Table 5: Uses of DNT resolving in possible presence of 2,4-DNT in articles. “Form of DNT” specifies the percentage of 2,4-DNT when a mix of isomers is used in the manufacture process. Table adjusted from Technical report (2010).

Use	**Description**	**Transformation during use**	**Form of DNT**	**Presence of DNT in the final product**
Manufacture of TNT explosives (2,4-DNT impurity)	Mining & Demolition	No	Technical grade	<1 % as impurity
Manufacture of explosives	Mining & Demolition	No	‘Pure’ 2,4-DNT (DNT 95+) & technical grade DNT (65/50))	<1 % as a melting/ solidification moderator; a few % in dynamite (old use)

[23] Also known as Octogen.

Manufacture of propellants	Manufacture of weapons and ammunition	No	DNT 95 (or higher) technical grade (DNT 80)	2.5-17 %
Recycling of explosives and ammunition	Manufacture of weapons, explosives and ammunition	No	Technical grade	<1 % as impurity
Manufacture of propellants for automotive airbags & seat belt pre-tensioners	Manufacture of explosives and accessories for motor vehicles	No	Unknown	See "Manufacture of propellants"

Seat belt pre-tensioners and airbags

It has been confirmed in the consultation (#3526) that 2,4-DNT is used in seatbelt pretensioners, although in smaller quantities than in the Dossier Submitter's original estimation. Therefore, it is plausible that car repair workers could be exposed to 2,4-DNT following any accident when repairing a vehicle and replacing the seatbelt instillation. This could happen on many separate occasions and thus the exposure of an individual worker could be longer term.

2.6.2 Consumer exposure assessment

Propellants in small arm and artillery ammunition

According to ECHA (2010) there are some literature referring to DNT in gunshot / post-blast residues (studies cited in Joshi et al. (2009)). Technical report (2010) refers to a study of Walsh et al. (2009) where it was shown how military training with artillery produces excess propellant that is burned on the training range can result in point sources containing high concentrations of unreacted propellant constituents such as nitroglycerine and 2,4-DNT. Both are found at firing positions and propellant disposal areas.

Exposure of military personnel and therefore the use of artillery or other large weapon system applying 2,4-DNT containing propellants is outside the scope of this restriction proposal and only discussed to extent it benefits the overall assessment of propellant use in small arms. Background of military use and discussion of exposure potential is discussed in Annex 1.

Firing point or firing position residues are a function of the efficiency of the weapon system and the composition of the propellant. Especially larger weapon systems with longer barrels, rifled barrels or larger propellant loads consume propellants more efficiently, whereas shorter barrels and smaller propellant loads leave relatively more residues (Walsh et al., 2011, EPHW, 2019) Evidence of post-blast residues in the vicinity of the barrel (within meters) have been reported in the literature. 2,4-DNT is found embedded in fibrous propellant post-blast residues (Figure 2). The weapon systems mentioned to produce 2,4-DNT residues are listed in Table 6. From a life-cycle point of view, the use of 2,4-DNT containing propellants may also eventually lead to occupational exposure in military waste disposal and recycling facilities (Letzel et al., 2003).

Table 6: Weapon systems producing releases of 2,4-DNT.

Weapon system		Propellant	Rounds	Residues /round (mg)	Source	Consumption efficiency	Compound remaining
Howitzers	105 - mm	M1-I & II	71	34	Walsh et al. (2009)	N.A.	N.A.
	105 - mm	M1	22	6.4	Walsh et al. (2009)	N.A.	N.A.
	155 - mm	M1	60	1.2	Walsh et al. (2005)	N.A.	N.A.
Tank (leopard)	105 - mm	M1	90	6.7	Ampleman (2009)	99.998 %	0.0022 %
Machine gun	7.62- mm	WC846	100	0.0018	Walsh et al. (2012)	99.95 %	0.05 %

Propellant use

2,4-DNT is used as an energetic compound in nitrocellulose (NC) which is the most common propellant. Propellants are classified by the major energetic constituents. For the NC based propellants, NC alloyed with or without DNT is known as single base propellant. These are typically used with howitzer and tank munitions. Double-base propellants contain nitroglycerine and may contain DNT. These are used with mortar, small arms, and rocket munitions. They burn faster than single-based propellants. Triple-base propellants contain nitroguanadine, which burns cooler than other propellant compounds while delivering comparable barrel pressures. Other energetic components in triple-base propellants include nitroglycerine and in some cases DNT. These propellants tend to be used with long-barrelled, large-calibre weapons systems (Walsh et al., 2011)

When a gun or rocket is fired, the combustion of the propellant is never complete. Energetic residues will be deposited on the ground from the end of a gun barrel or behind a rocket launcher. These residues will contain the constituents of the original propellant formulation, typically (but not always) in the ratios of the unburned propellants. Combustion efficiency is influenced by barrel length, combustion temperature and pressure, the propellant formulation, and propellant age. Small arms thus cover such common weapon systems as pistols, rifles, and machine guns. As small arms projectiles are generally non-detonating, we looked only at firing points. Combustion efficiencies are according to the literature in the range of 0.002 to 0.5 %, depending on the used weapon type and amount of DNT in the propellant (Table 7).

The tasks/activities assessed for possible exposure were inhalation and/or dermal exposure to 2,4-DNT when loading and unloading the weapon, firing and deposition to the ground and exposure via environment.

ES 1: Military use, information from scientific studies

ES1 consists of the following contributing scenarios:

- CS 1: Loading and unloading – dermal exposure

- CS 2: Firing – inhalation and dermal exposure
- CS 3: Via environment/contaminated soil – dermal exposure

The difference in deposition rate means that higher temperature and pressure are resulting in the tank gun barrel, leading to a cleaner combustion with smaller amounts of residues. This could be explained by the fact that the barrel is longer for a tank than for the howitzer leading to more time at elevated pressure and temperature leading to a cleaner combustion.

However, for this report no specific exposure assessment was conducted for the military uses. Further details of 2,4-DNT used in military, especially in artillery ammunition, is provided in Annex 1.

ES 2: Exposure scenario for civilian small arms use in hunting/shooting

ES2 consists of the following contributing scenarios:

- CS 1: Loading and unloading – dermal exposure (contamination inside the gun)
- CS 2: Firing – inhalation and dermal exposure
- (CS 3: Via environment/contaminated soil – dermal exposure)

Small arms cartridges may contain 2,4-DNT. Based on the studies from Walsh et al. (2007) and Walsh et al. (2011), the amount of 2,4-DNT in propellant of rifles and shot gun cartridges is between 0.27-4 g. According to some webpages of companies selling ammunition cartridges, the weight of rifle and shot gun cartridges are 3.6-28 g and 28-60 g respectively. In some publicly available Safety Data Sheets (SDS), the amount of 2,4-DNT is in maximum 2 % (w/w) in small arms cartridges. It is unsure whether these articles that contain 2,4-DNT are sold in the EU market. In the exposure assessment the weights of the cartridges for rifles and the concentration of 2 % for 2,4-DNT is used, even though considered to be as a worst case. The rate for deposition in hunting (rifles) is probably much worse than in artillery firing since it depends on how well the combustion occurs. Longer barrel gives better combustion. Based on the studies performed by Walsh et al. (2007, 2011), the estimated deposition rate is between 0.05-0.5 % for small arms.

Hunting and sport shooting may occur outside and training for hunting and sport shooting in indoor shooting range. In the simplified calculations it is assumed that for hunting that occurs outside, the duration of the exposure/activity is 2.5 hours (10 shots). For indoor shooting it is estimated that 50 shots are fired in 1 hour. Frequency of the hobby activity is assumed to be frequent (>15 times per year) and no correction factors are utilised in estimations. For both activities it is assumed that 80 or 100 % of the unburnt deposition is released to the surrounding air. The estimated airborne concentration of 2,4-DNT in outdoor and indoor is compared to the current lowest national OEL for 2,4-DNT in Europe and also to the long-term DNEL for general population that the registrant of DNT has derived in his dossier.[24]

[24] OELs and DNEL according to GESTIS International Limit Values database and registration dossier for DNT (https://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx and https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/30782/7/6/2 , respectively). ECHA notes that 2,4-DNT is a non-threshold carcinogen for which it was not possible to determine a DNEL, however the DNEL used by the registrant of DNT has been used as a comparison with the use of the national OEL value.

For the general population, long-term DNEL is more suitable than acute DNEL since the substance is a carcinogen. The calculations are presented in the Table 8. High exposure to lead has been measured for workers and shooters in shooting galleries during 2000-2014 in Finland (Kiilunen, 2017). In case the bullets include 2,4-DNT, exposure to 2,4-DNT in shooting galleries is possible. However, the exposure is dependent on weapon and bullet type, exposure duration, frequency of shooting, room ventilation and other activities/shooters in the room at the same time. The exposure to 2,4-DNT in outdoor hunting is possible, but not very likely. Dermal exposure to organic gunshot residues, which includes 2,4-DNT, was studied qualitatively by Hofstetter et al. (2017) and the study indicated that residues can be found from hands and other part of the upper body of the shooter including clothing.

Conclusions

On the basis of the calculations provided in Table 7 and Table 8 the exposure via inhalation is possible for people engaging in hunting or shooting activities. When the estimations of exposure during shooting outdoor (hunting) is compared to the OEL (8 hour) or long-term DNEL of 2,4-DNT, the calculated risk characterisation ratios (RCR) are from 0.002-0.3 and 0.05-6 respectively. The estimated RCRs for indoor shooting are higher than in outdoor being from 0.1-11 and 2->200 respectively.

The Dossier Submitter surmises that the calculations provide evidence of the exposure and risk and the worst-case scenario should be considered as the substance is a non-threshold carcinogen. Exposure via skin is possible for hands, fore arms and face, however, no estimations for this exposure route has been made. Finally, exposure for humans via environment can also be considered possible, but unlikely.

Table 7: Propellant mass, DNT-concentration and unburnt propellant and DNT in various military and small-arms weapons. MG = machine gun.

Weapon	Amount	DNT conc.	Unburnt and deposit	Unburnt DNT	Deposit area	Rounds	Conc.	Conc.	Source
	g	g	mg	%	m^2		mg/m^2	mg/kg	
Tank firing 105-mm	3000	300	7.89	0.0026	929	90	0.76		Ampleman et al. (2009)
Tank firing 105-mm	6000	600	15.78	0.0026	929	90	1.55		Ampleman et al. (2009)
Artillery firing 105-mm		42	34	0.08					Ampleman et al. (2009)
Artillery/howitzer firing 105-mm		varied	varied	0.3-0.05				0.4-43	Diaz et al. (2008)
Artillery firing 155-mm		275	1.2	0.001					Ampleman et al. (2009)
Artillery firing (Nicolet study)	840	0.8	1.84	0.23					Ampleman et al. (2009)
Artillery firing (Nicolet study)	467	0.47	1.83	0.39					Ampleman et al. (2009)
Small arms (7.62-mm MG)		0.27	1.50	0.56					ERDC/CRREL TR-11-13, Walsh et al. (2011)
Small arms (7.62-mm MG)		4	0.0018	0.05					Walsh et al. (2007)
Small arms (pistol, rifle, machine gun, mounted arms)								0.4-17	ERDC/CRREL TR-11-13, Walsh et al. (2011)

Table 8: Estimations for inhalation exposure to 2,4-DNT shooting indoors and outdoors (i.e. sport shooting and hunting). Table a) exposure estimations compared to the OEL (8 hour), b) to the long-term DNEL derived by the registrant for DNT.

Activity	**N**	**bullet**	**DNT (2%)**	**Unburnt DNT**	**Unburnt and deposit**	**Release to the air**	**Duration/Exposure time**	**Volume outdoor/ room ***	**Dilution factor****	**Conc in breathing zone**	**Conc. (8 h)**	**OEL (8h)*****	**OEL-based RCR**	**Conc. (6h)**	**DNEL long-term******	**DNEL-based RCR**
		g	g	%	mg	%	h	m^3		mg/m^3		mg/m^3			mg/m^3	
Least exposure: shooting (outdoor)	10	3.6	0.72	0.05	0.36	80	2.5	100	2.5	0.003	0.0004	0.15	0.002	0.0005	0.009	0.053
Worst case: shooting (outdoor)	10	28	5.6	0.56	31.36	100	2.5	100	2.5	0.31	0.039	0.15	0.26	0.052	0.009	5.81
Least exposure: shooting (indoor)	50	3.6	3.6	0.05	1.8	80	1	20	0.6	0.120	0.015	0.15	0.10	0.020	0.009	2.22
Worst case: shooting (indoor)	50	28	28	0.56	156.8	100	1	20	0.6	13.1	1.63	0.15	10.9	2.18	0.009	242.0

* Outdoor is considered as 100 m3 and shooting gallery as 20 m^3; ** Dilution factor is a factor for air volume changes outdoor/indoor, the value is from ECETOC TRA Consumers V.3.1; *** Five countries in Europe have an OEL for 2,4-DNT. The range for the national OELs is 0.15-1.0 mg/m^3 (8h), for 15 minutes there is only 0.3 mg/m^3; **** The long-term DNEL is derived by the registrant.

Seat belt pre-tensioners and airbags

Technical report for 2,4-DNT (2010) indicated the possibility that the substance could be used in both air bags and seat belt pre-tensioners. Suppliers and manufacturers at the time confirmed that they do not use 2,4-DNT in the articles for the European market. However, some manufactures have provided information of the use according to Article 33 of REACH, e.g. Toyota and Ford[25]. This use has been confirmed in the consultation (#3526).

Seat belt pre-tensioners include electronic, mechanical and pyrotechnic solutions to hold a passenger firmly on their seat at a start of a collision, allowing a controlled contact with the inflated airbag. 2,4-DNT is used in the pyrotechnic version of pre-tensioner. An explosive charge causes the gas generator to produce a volume of gas and thus pressure which acts on a mechanical linkage to pull the seat belt. The pre-tensioner needs replacing after deployment. The deployment consumes the explosive in the seat belt assembly. Ford advises that potential exposure to customers is minimised if the car and its parts are used, repaired, maintained and disposed as intended[26]. Disposing an end-of-life vehicle legally in the European Union takes place in Authorised Treatment Facilities (ATF). Other information on the exposure than the remark above is not available to ECHA.

These uses have not been notified to ECHA according to Article 7(2). A search of the SCIP database has indicated motor vehicle waste includes 2,4-DNT, which supports the discussion above.

A specific exposure scenario had been created for this use: **ES 3 Use in safety equipment in car** (airbags and pre-tensioners in seat belts). This scenario is relevant only during a sudden crush or stop when the system reacts and was only included to illustrate a risk using the available threshold based national OELs and not related to the non-threshold effects. Therefore, this has been removed from the report to avoid confusion, but has been transferred to Annex 2 for completeness.

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[25] https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwi3ytek6tHsAhVJsaQKHZ2BC8wQFjAAegQIAhAC&url=https%3A%2F%2Fwww.toyota.hu%2Fdownload%2Fcms%2Fhuhu%2FToyota%2520Aygo_SVHC%2520Information_032019_tcm-3033-1572338.pdf&usg=AOvVaw15sytWN_78pxTfiJITxILL

[26] https://www.ford.co.uk/content/dam/guxeu/uk/useful-information/reach/Art-33-1-Information-Example-U502-Explorer.pdf

Other consumer uses

There are likely to be further potential uses in articles (not notified according to Article 7(2)), but there is very limited information on any potential exposures.

2.6.3 Environmental exposure assessment

In relation to the uses discussed, 2,4-DNT is mainly found on the topsoil layer where it accumulates when using propellants in small arms ammunition and heavy weapons such as artillery (Walsh et al., 2011). Further information on environmental exposure assessment especially in military use is available in Annex 1.

2.6.4 Summary of the existing legal requirements

Under REACH, 2,4-DNT was included in the candidate list for authorisation (13/01/2010; ED/68/2009) and included into Annex XIV of REACH (Commission Regulation (EU) No 143/2011) on the basis of art 57(a) Carc. 1B. with a sunset date of 21/08/2015. By this sunset date ECHA has not received any application for authorisation. It should be noted placing on the market or the use of an article which contains an Annex XIV substance is not subject to the authorisation requirement (See AfA Q&A nr: 0564[27]). Therefore, imported articles are not covered by authorisation.

REACH has several requirements for substances on the candidate list including notification of its presence in articles if the concentration of the substance is > 0.1 % and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1 % by weight of the substance in question (Article 33(b)).

2,4–DNT as a substance or a constituent of other substances, or mixtures containing it $\geq$ 0.1 % are restricted for supply to the general public (Annex XVII entry 28, appendix 2).[28] This does not apply to medicinal products for human or veterinary use, as defined by Directive 2001/83/EC and Directive 2001/82/EC, respectively; cosmetic products as defined by Directive 76/768/EEC; the following fuels and oil products: motor fuels which are covered by Directive 98/70/EC, mineral oil products intended for use as fuel in mobile or fixed combustion plants, fuels sold in closed systems (e.g. liquid gas bottles); artists' paints covered by Regulation (EC) No 1272/2008.

2,4-DNT is not classified as explosive itself but is further processed to 2,4,6-TNT, which is then used in explosive articles for several civilian uses. There are some indications that there are 2,4 DNT impurities in TNT but the concentrations are unknown. One reference states that 2,4-DNT was an impurity at a concentration of 0.08%[29]. As DNT is volatile the concentration can be expected to reduce over time.

Several existing EU-wide measures apply to the manufacture, storage and use of explosives:

- SEVESO Directive (2012/18/EU), the classification of TNT as explosive category 1.1 s (P1a explosives) triggers lower tier requirements at 10 tonnes and upper tier requirements at 50 tonnes related to major accident hazards.

[27] https://echa.europa.eu/support/qassupport/browse//qa/70Qx/view/scope/reach/authorisation.
[28] Commission Regulation (EU) No 109/2012 of 9 February 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances)
[29] R. P. Murrmann Composition and Mass Spectra of Impurities in Military Grade TNT Vapor (1971)

- Directive 2014/28/EU[30] on making available on the market and supervision of explosives for civil uses. This Directive requires that each explosive must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment under normal, foreseeable conditions – chemical composition must be taken into account.
- Under the Industrial Emission Directive (2010/75/EU), a substance is regarded as 'hazardous' as long as it is classified. Production of explosives is covered in Annex I and so all the appropriate preventive measures are taken against pollution and the best available techniques are applied, for example. Such sites must also be permitted.
- Under the Waste Framework Directive (2008/98/EC), wastes containing 2,4-DNT would be regarded as hazardous waste.
- The worker protection measures (CAD and CM Directive) apply to protect workers using 2,4 DNT and TNT. Several national OELs also are in force as mentioned in the BD.

Therefore, the Dossier Submitter has assessed that the manufacture of explosives from 2,4-DNT as well as any impurities is well managed by the existing legislation. In addition, other articles containing 2,4-DNT (such as seat-belt tensioners, electronic equipment) is well managed under the existing legislation on worker protection.

The Dossier Submitter assessed this may not be the case with professional uses for the following reasons:

- Professional workers who are using chemicals outside of a controlled workplace could be considered similar to consumers in their capacity to implement risk management measures. These uses are carried out in the context of commercial activities and assumed to take place in most towns of a certain size, by multiple actors each at low scale e.g. local garage, small cleaning businesses. The following list includes typical examples of businesses involving chemicals, which would be considered as "widespread use by professional workers":
    - ➢ Building and construction business with broad variety of activities (mostly micro companies)
    - ➢ Maintenance services for office /household equipment
    - ➢ Indoor cleaning services for all kinds of buildings
    - ➢ Façade cleaning services
    - ➢ Car wash and other car care services
    - ➢ Hairdressing and other beauty services
    - ➢ Health care services
- Professional workers are more likely to have limited knowledge of the risks and difficulties in ensuring risk management and preventing exposure of consumers for whom they are providing a service. It is unlikely an OEL would be helpful as the only possible RMM is likely to be PPE/RPE or mobile extraction, all of which are not highly efficient in reducing risk; exposure to the environment will also be difficult. In addition, the self-employed are also not covered.

[30] DIRECTIVE 2014/28/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast).

Therefore, the scope of the restriction assessed by the Dossier Submitter is only related to consumer and professional uses.

2.7 Risk Characterisation

According to the EU RAR (2008) the most probable route of human exposure to 2,4-DNT is inhalation and dermal contact of workers involved in the production and use of 2,4-DNT containing explosives. Due to evidence that 2,4-DNT containing fibres are deposited on clothes of the operators of artillery guns, an inadvertent ingestion is also a possible source of exposure in addition to dermal and inhalation exposure. Inhalation exposure is also concern in civilian small arms use, such as hunting and sport shooting, if the ammunitions used contain 2,4-DNT. The use of 2,4-DNT in explosive articles in mining and demolition purposes is also known. However, no indication for current use of such articles in EU was found during the screening done for this report.

The ammunition use on fixed ranges during training leads to the accumulation of 2,4-DNT in the top-soil layer, thus dermal exposure from handling soil may be possible. In addition, 2,4-DNT may be taken up by plants and expose humans through the environment. Furthermore, the use of 2,4-DNT in vehicle safety systems may lead to exposure of the safety personnel attending accident sites and vehicle repairing technicians replacing these safety systems. Also, roadside accumulation of 2,4-DNT may be leading to uptake of plants and exposure to humans through the environment, however, information of 2,4-DNT roadside accumulation is not available.

As the exposure potential of 2,4-DNT as softener / plasticiser in plastic articles and more in general as additive in any plastic material can be considered high and it seems to diffuse easily in the plastic matrix and partition from surface to contact medium (water, saliva or skin), the risk of exposure from using plastic sample bottles cannot be excluded.

In the (EU RAR, 2008) the conclusion was that there is a need for limiting the risks because of concerns for carcinogenicity and mutagenicity as a consequence of inhalation and dermal exposure arising from all worker scenarios. There was no conclusion for risk reduction measures beyond those which are being applied already for the general public because exposure of consumers is not assumed to exist. In humans exposed via the environment there is a need for limiting the risks because of concerns for carcinogenicity and mutagenicity as a consequence of oral exposure arising from one manufacturing site.

According the Annex I paragraph 6.5, ECHA guidance Part E (ECHA, 2016) and R.8 (ECHA, 2012) and the 'Common approach of RAC and SEAC in opinion development on applications for authorisation'[31], the adequate control route is not possible for a non-threshold substance (such as 2,4-DNT)[32]. Based on this position, the Dossier Submitter is of the view that 2,4-DNT poses a risk to human health if incorporated in articles that is not adequately controlled.

Therefore, it is the Dossier Submitter's view that a risk of carcinogenicity from exposure to 2,4-DNT for military personnel and other users of artillery ammunition cannot be excluded. Furthermore, aggregated exposure to 2,4-DNT from firing artillery ammunitions and other explosive articles such as small arms ammunition cannot be excluded through environmental

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[31] https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf

[32] In practice, this means that applicants for authorisation have to demonstrate the rationale for an authorisation via the so-called socio-economic route. RAC will analyse if operational conditions and risk management measures ensure that the exposure levels are as low as technically and practically possible, however.

accumulation and subsequent human exposure. Finally, a risk to humans from imported articles cannot be excluded.

3. Justification for an EU-wide restriction measure

Based on the following reasons a Union-wide action to address the risks associated with EU manufactured or imported articles containing 2,4-DNT seems warranted:

- To ensure a harmonised high level of protection of human health across the Union;
- To ensure the free movement of goods within the Union, where relevant.

The Dossier Submitter considers that taking regulatory actions at a national or local level would neither be effective nor efficient, since these authorities would have even less access to information about current uses of 2,4-DNT in articles.

4. Baseline

4.1 Problem definition

Technical DNT is currently manufactured in the EU as a non-isolated intermediate in quantities of 540 000 to 810 000 tonnes per year. The majority of this use is in the manufacture of TDI.

In US, total production of 2,4-DNT in 2016 was in range of 11-45 tonnes (EPA CDR 2016). Data from 2013 lists 14 plants producing, processing or using 2,4-DNT at minimum of approximately 150 tonnes to maximum of 1 400 tonnes per year in US.

The use of 2,4-DNT in production of articles in the EU is subject to authorisation requirements under Title VII of REACH. At the time of the writing of this report, no applications for authorisation were received. Authorisation requirements do not apply to imported articles and it is thus possible that articles containing 2,4-DNT are produced outside the Union and subsequently imported in the EU, causing a risk to human health.

4.2 How the situation would evolve without any regulatory measures

Without a restriction there would continue to be articles imported for occupational uses and potentially for consumer uses. This could leave consumers and workers exposed to a carcinogen for which a safe threshold cannot be established. Furthermore, this would lead to a perverse situation in which the premise of REACH to substitute SVHC by suitable alternatives or technologies, where these are economically and technically viable, would not apply to imported articles.

5. Impact assessment

5.1 Scope of the impact assessment

The impact assessment of the proposed restriction is based on the premise that there are possibly articles placed on the EU market that contain 2,4-DNT (seat belt pre-tensioners, plastic sample bottles, ammunition, refractory materials, and others).

5.2 Potential restriction options

A number of potential restriction options were considered by the Dossier Submitter, see Table 9. For all options a limit value of 0.1 % of 2,4-DNT (weight by weight) is proposed as a practical value used already for the notification of substances in articles according to article 7(2) of the REACH Regulation.

Table 9: Considerations related to potential restriction options

Potential restriction option		Risk considerations	Impact considerations	Efficiency considerations	Risk reduction considerations
1	Restriction on placing on the market of all articles containing 2,4-DNT	No risk assessment made to industrial uses as it is assumed that industrial uses and uses of explosives are well controlled (however, no specific assessment has been made).	Some impacts to importers of ammunitions containing 2,4-DNT and to manufacturers of explosives using DNT. Low impacts to other actors as low number of articles foreseen to be in scope	Efficient as test methods exist. Some decrease of the efficiency is possible in case Member States use article 2(3) of REACH to allow exemption to this restriction in the interest of defence.	High, even though Member States may use article 2(3) of REACH to allow exemption to this restriction in the interest of defence.
2	Restriction of placing on the market of articles containing 2,4-DNT of use by general public or specified uses by workers (such as professional uses) under article 68(1) of REACH.	Risk to most vulnerable populations and professional workers addressed. It is assumed that industrial uses and uses of explosives would be well controlled.	Low impact as low numbers of articles foreseen to be in scope and as no applications for authorisation were received it is assumed adequate substitutes exist. No impact on industrial users.	Efficient as test exists.	Medium as military ammunition and explosives are not covered.
3	Restriction of placing on the market of articles containing 2,4-DNT of use by general public under article 68(2) of REACH.	Risk to most vulnerable populations addressed but it could not cover professional uses. It is assumed that industrial uses and uses of explosives would be well controlled.	Low impact as low numbers of articles foreseen to be in scope and as no applications for authorisation were received it is assumed adequate substitutes exist. No impact on professional or industrial users.	Efficient as test exists.	Low to medium as military ammunition, explosives and other professional uses not covered.

In addition, the Dossier Submitter considers that the non-REACH legislation summarised in Table 10 is not suitable for managing the identified risks (taking account of potential exemptions).

Table 10: Considerations of non-REACH EU legislation for controlling articles containing 2,4-DNT

EU legislation	Considerations
Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys	Substances classified as carcinogenic 1B are prohibited in toys in concentrations equal to or above 0.1 %, unless a safety assessment has been carried out showing it is safe. *Conclusion: Proposed limit will be the same as in the toys Directive.*
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment	2,4-DNT is not currently restricted in electronic equipment. There are indications in the SCIP database of inclusion of the substance in electronic articles. *Conclusion: The substance could be added to ROHS but until it is there is no overlap with the proposed restriction. It is assessed to be more efficient to use this restriction to prevent its use than having an additional measure but the Commission could eventually decide to remove the exemption and cover under ROHS.*
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.	2,4-DNT is not currently allowed in plastic food contact materials (not in the positive list in Commission Regulation (EU) No 10/2011) but other materials are not covered. *Conclusion: It is more efficient to restrict in this measure.*
Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses.	This Directive requires that each explosive must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment under normal, foreseeable conditions – chemical composition must be taken into account. *Conclusion: This provides control of the substance used to produce explosives and the use of the explosive (including any impurities).*
Industrial Emission Directive (2010/75/EU),	Production of explosives is covered in Annex I and so all the appropriate preventive measures are taken against pollution and the best available techniques are applied, for example. Such sites must also be permitted. *Conclusion: This provides additional controls on environmental exposure during manufacture of explosives from 2,4 DNT.*
SEVESO Directive (2012/18/EU),	The classification of TNT as explosive category 1.1 s (P1a explosives) triggers lower tier requirements at 10 tonnes and upper tier requirements at 50 tonnes related to major accident hazards. *Conclusion: SEVESO will provide additional controls for explosives made in higher concentrations.*

EU legislation	Considerations
Regulation (EU) 2017/745 [33]of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU Regulation 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions	Devices, or those parts thereof or those materials used therein that are invasive and come into direct contact with the human body, (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain substances which are carcinogenic of category 1B, in a concentration that is above 0,1 % weight by weight (w/w) unless its justified where justified based upon: (a) an analysis and estimation of potential patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit- risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. *Conclusion: Exempt the use in medical devices.*
Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.	For substances classified as carcinogenic 1B, employers are obligated to minimise worker exposure to these agents as far as possible and must arrange for medical surveillance of workers exposed to these substances. Self-employed persons are not covered. *Conclusion: This legislation is expected to provide control of exposure for industrial uses (see xxx of discussion on professional uses).*
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.	2,4-DNT is restricted in Annex II (Prohibited Substances) in the Cosmetics Products Regulation but as the Cosmetics regulation does not cover articles, there is no double regulation with this restriction. *Conclusion: No need for any exemption.*
Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food	This regulation does not currently allow 2,4-DNT, for example in plastic food contact materials as there is a positive list which does not include the substance. *Conclusion: Although it makes no difference, for the current measure, it would be useful to specify this for clarity.*

[33] Enters into force in June 2021.

5.3 Proposed restriction

Considering the baseline analysis in Section 5.2, the best option appears to be RO2. RO1 would entail higher costs but would probably entail a similar risk reduction as industrial uses and uses as explosives are assumed to be well controlled.

Further points to consider in the proposed Restriction Option are:

- Article 69(2) of REACH applies to the use of articles, so the restriction covers both placing on the market and use to address the risk.
- Related to the concentration limit, it is proposed to use the same concentration limit as in the notification of substances in articles according to article 7(2) (SiA notifications) and for CMRs in toys.
- Related to the use in explosives, it is assumed that these are well-regulated, e.g. according to Directive 2014/28/EU, and since relevant measures are in place for handling of explosive these should limit any exposure to 2,4-DNT to workers or the environment. It is therefore proposed to exempt the relevant manufacture and use of the substance from the restriction (including its impurities in TNT). However, it was discussed during the opinion making that the definition of explosive was wide and would include both pyrotechnical articles (fireworks) and ammunition. Therefore, it was clarified that these types of articles would be in scope – fireworks as they could lead to consumer or professional exposure, and ammunition as ammunition for non-military and non-police use can also lead to exposure of consumers.
- Following the reasoning in the lead in ammunition restriction proposal, it is proposed to exempt military and police use of ammunition from this restriction. Information received during the consultation indicated that there is continued use of 2,4-DNT in the production of propellants later used in the production of (military) ammunition and therefore it is clear this exemption is required. It is proposed therefore to take into account the wording of the definition in Directive 2014/28/EU relating to the making available on the market and supervision of explosives for civil uses (recast) which states that the *Directive shall not apply to: (a) explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police*.
- Related to exemptions, according to the analysis presented in Table 11 it is proposed to exempt articles covered by Directive 2009/48/EC on the safety of toys; Regulation (EU) 2017/745 on medical devices; and Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.
- It is proposed to add an exemption for second-hand articles where this has been previously discussed in general to cause difficulties in enforcement and high costs if these are not exempted. The necessity for derogating second-hand articles is best exemplified by the use of 2,4-DNT in the seat pretensioners of used cars. If such cars were not derogated, then the placing on the market of a second-hand car would require proof that this car does not contain 2,4-DNT. Given that i) second-hand markets are often less formal, ii) resellers often do not have available all information about the manufacturing of the article, and iii) mandatory testing of potential parts containing the substance is highly impractical, then the conclusion is that this would impose a disproportionate burden on second-hand markets.
- Related to definitions, the Dossier Submitter is proposing:
    - Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for

civil uses defines explosives as the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations.

  - The current proposal defines professional use as uses by workers that take place outside of industrial premises and where fixed risk management measures cannot be used. The concerns that have been raised by the RAC and the Forum on this definition relate to what is an industrial premises and why did the restriction not cover all uses but exempting uses in industrial installations (for example). The REACH legal text differentiates between industrial and professional use [activity] in definitions 13, 25 and 35, as well as section 6 of Annex VI. In Annex XVII also the terms "industrial installation" and activity of a "professional outside industrial installations" are used. However, no detail is given on the difference between the two and clarification is needed to support companies in this decision. Based on the existing definitions outside REACH and the possible mismatch with the intended scope, the Dossier Submitter proposes to align the wording with REACH.

- Related to the transitional period, as there is no EU production of articles, there is no need to transition to alternatives or stocks. If there are any imported articles, time is needed for importers to transition to different articles not containing 2,4-DNT. Therefore, it is assumed 12 months would be a sufficient transitional period.
- In as far as such exposures occur, the proposed restriction would also decrease the exposure of humans via the environment.

5.4 Available information on alternatives

ECHA has not received any applications for authorisations for uses of 2,4-DNT. Two SiA notifications were received for the substance of which one use has in the meantime ceased and the other use (as an intermediate) is proposed to be derogated. Based on this evidence, the Dossier Submitter assumes that there are suitable alternative substances or technologies available for 2,4-DNT in articles covered by the proposed restriction. The Dossier Submitter reasons that otherwise more notifications for uses in articles which historically used the substance, registrations, and perhaps even applications for authorisation of 2,4-DNT uses would exist. As there is however no known EU production of articles using the substance, there is no need for EU companies to transition to alternatives or to deplete their stocks.

For example, consider the specific use of 2,4-DNT in seat belt pretensioners, which is currently not done in the EU (or else applications for authorisation for such uses would have been received). This suggests that EU car manufacturers have found suitable alternatives for this particular use or import parts containing 2,4-DNT from outside the EU. In the latter case, substitution costs would accrue to non-EU entities and would only represent a welfare cost to the EU if non-EU producers had sufficient market power to pass through any production price increments to EU companies. In a highly competitive sector such as the automotive industry this is very unlikely to happen.

During the consultation on the Annex XV report, it was indicated that an alternative for 2,4-DNT in seat belt pretensioners was nitroglycerine (#3526). The Dossier Submitter notes that nitroglycerine is classified in Annex VI of the CLP regulation: Unst. Expl. (H200), Acute Tox.2 (H300)*, Acute Tox. 1 (H310), Acute Tox. 2 (H330), STOT RE 2 (H373)**, Aquatic chronic 2 (H411).

By analogy the Dossier Submitter considers that for a wide range of possible uses in articles, suitable alternatives must exist. It is however not possible to identify the uses in which 2,4-DNT was historically used and got replaced a decade ago.

The Dossier Submitter further notes that if there are imported articles using the substance, time may be needed for importers to ensure the transition to alternative articles not containing 2,4-DNT. Given the absence of uses in the EU, the Dossier Submitter presumes that a 12-month transition period would be sufficient to allow for substitution to take place.

For the reasons listed above, the Dossier Submitter is confident that there are technically and economically feasible alternatives to 2,4-DNT available and that substitution costs accruing from the implementation of the proposed restriction, if any, there be very limited.

5.5 Economic impact

Overall, the compliance costs of EU actors in the supply chains using 2,4-DNT in articles are considered to be very small. No costs are expected for manufacturers, importers of the substance or mixture because there is no direct article manufacturing in the EU (as no applications for authorisation were received). There may be some costs for importers of articles, having to re-source alternative products, but as discussed above such costs are likely to be negligible.

For consumer uses of 2,4-DNT in articles, it is assumed there are suitable alternatives; for professional uses of 2,4-DNT in articles the situation is less clear. An RIVM study on alternatives for phthalates plasticisers lists alternatives for its use in ammunition as a plasticiser and deterrent (burning rate regulators), which could also be considered for the similar use of 2,4-DNT (RIVM, 2013).

In addition to the above, the Dossier Submitter is of the view that the potential for loss of employment or changes in price for end users will also be negligible.

In sum, the total economic impact of a restriction on 2,4-DNT in articles covered by this proposal is expected to be minimal. The assumptions on the availability of alternatives, loss of employment or changes in price for end users were tested in call for evidence and no information was received that questioned these assumptions.

5.6 Human health impact

According to the EU RAR (2008), there is no valid human epidemiology study available. However, two studies (Seidler et al., 2014, Brüning et al., 1999) support the hypothesis that occupational exposure to DNT may be carcinogenic, since excess cancer mortality observed among DNT-exposed workers is consistent with findings from experimental studies of DNT exposed animals. These studies associate an excess of hepatobiliary cancer and both urothelial cancer and renal cell cancer with jobs where workers were supposedly exposed to purified 2,4-DNT and miners supposedly exposed to technical grade DNT, respectively.

Whilst the Dossier Submitter notes that the willingness-to-pay for avoiding cancer is substantial, no quantitative assessment of the benefit expected from this restriction could be undertaken.[34] This is for three reasons. First, considering the assumptions made in the costs assessment, there are unlikely to be (m)any workers or consumers exposed. Second, typical

[34] See SEAC's Reference willingness-to-pay values for monetising chemicals health impacts.

exposures to 2,4-DNT from various articles are not known. Third, there is no known dose-response function that would link exposure to 2,4-DNT to the associated types of cancer.

The Dossier Submitter considers therefore that the benefit of the proposed restriction is due to its preventive value, as it would prevent future uses of the substance in articles, and thus avoid regrettable substitution and potential risks to workers and consumers in the EU.

5.7 Other economic issues

No social, wider economic and distributional impacts have been identified.

5.8 Other issues

5.8.1 Effectiveness

Risk reduction capacity

The proposed restriction reduces potential risks from 2,4-DNT in articles covered in this proposal to an acceptable level within a reasonable period of time.

Targeted

The restriction is targeted to the effects or exposures that are of most concern, e.g. consumer and professional uses.

Proportional to the risk

The restriction is assumed to impose very low costs to reduce a potential risk; given the information at hand, it is assumed that the measure is proportionate to the risk.

5.8.2 Practicality

The proposed restriction is practical because it is implementable, enforceable and manageable as the proposed restriction is easy to understand and communicate down the supply chain and can be enforced.

Implementability

The restriction is implementable as companies can test for a concentration limit in an article or make it a condition of the contract for purchase not to have the substance present in the article. It is assumed that for any imported articles covered in this proposal containing the substance that there are alternative articles types. In addition, the proposed restriction gives sufficient time to the impacted supply chains to transition.

Enforceability

Enforcement authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. Testing and sampling methods exist for several matrices, including water, air, solid waste, explosives etc[35]. It is expected that suitable methods can be further developed to enforce the restriction.

[35] Hazardous Substances Data Bank (HSDB): 1144 - PubChem (nih.gov)

Manageability

The restriction is manageable by industry and authorities.

5.8.3 Monitorability

The efficacy of the restriction can be monitored through the EU Safety Gate (former Rapid Alert System for Non-Food Products (RAPEX)) system at EU level. National control campaigns may be launched as a mean to monitor the compliance, e.g. coordinated by Forum.

6. Assumptions, uncertainties and sensitivities

Assumptions in the cost assessment should be tested in the stakeholder consultation on the Annex XV dossier. It is clear that the extent of the use of the substance is a major uncertainty. However, the consultation on the Annex XV dossier is expected to test if the Dossier Submitters assumptions are correct. Moreover, the identified key uncertainty cuts in both direction since if there are less/more uses, then the benefit of preventing exposure from such uses will be lower/higher but also the costs of replacing the substance by alternative substances or technologies will be lower/higher.

The completeness of the use assessment should also be tested.

7. Stakeholder consultations

A call for evidence was held 27/1/21 to 10/3/21 (https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/27201/term); two comments were received, one giving further information on occupational exposure to 2,4-DNT (from production and handling of explosives) between 1990 and 2021. No additional information on uses or challenging the assumptions made in the restriction proposal was received.

The Dossier Submitter also consulted the European Defence Agency on the potential restriction.

8. Conclusion

The conclusion of the Dossier Submitter's assessment is to propose a restriction covering consumer and professional uses of 2,4-DNT to prevent any existing or future uses of the substance which would pose a risk to the users of the articles. To identify the most appropriate measure to address these risks, an analysis of risk management options (RMOs) was conducted, including regulatory measures under REACH, other existing EU legislation and other possible Union-wide RMOs and it was concluded that a restriction under REACH is the most appropriate risk management option.

A number of restriction options (RO) were assessed on the basis of the effectiveness, practicality and monitorability of these ROs and the following restriction is proposed, see Table 1.

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Annex 1: Use of 2,4-DNT in propellant mixtures

Summary

Propellants containing 2,4-DNT can be found both in small and large calibre ammunition. Trinitrotoluene (TNT) can contain 2,4-DNT either as an impurity or due to the recycling of 2,4-DNT containing ammunition or explosives for the use of manufacturing TNT. Some explosives may contain <1 % of 2,4-DNT as a melting/solidification moderator. 2,4-DNT may also have been used in some dynamite applications.

According to the screened literature, certain types of propellants utilised in artillery ammunition may contain up to 10-17 % of 2,4-DNT. The use and firing of artillery ammunition are a military activity. The vast majority of the literature on military uses of 2,4-DNT discussed in this report concerns practices and field experiments in the US and Canada. Exposure of military personnel or soil in EU is therefore unknown. However, in 2019, a group of Nordic countries together with experts from the US and Canada published a report that addresses the problem of field disposal of propellants and accumulation of 2,4-DNT in live-fire training fields.

Energetic residues containing 2,4-DNT can be found around the firing points of live-fire training places for the military because the combustion of the propellant is always incomplete. Furthermore, high levels of 2,4-DNT in the training areas can also be found in and around unexploded ordnances or places where unexploded ordnances are stored for disposal on the field. Training produces excess propellant as the amount of the propellant is adjusted for ballistic reasons at the range. Also, this excess is disposed at the field by burning, often on bare ground.

The risk of exposure for the military personnel handling and firing the artillery cannot be excluded on the basis of this assessment. There is a substantial literature (cf. Background) indicating that the incomplete combustion of propellants and the corresponding 2,4-DNT-related pollution on training ranges may lead to human exposure of 2,4-DNT. On military training ranges, 2,4-DNT is mostly accumulating in the top layer of the soil. Nitrocellulose fibres containing 2,4-DNT can be found on clothing of military personnel operating the artillery (i.e. artillerists). In addition to artillery firing points, small arms firing points have been found to be contaminated with 2,4-DNT. Environmental concerns relate to the fact that the substance, which is classified as Aquatic Acute 1 and Aquatic Chronic 1, is found in the top layer of the soil.

During the screening, a possible knowledge gap with regard to the extent of use and import of 2,4-DNT-containing artillery ammunition was identified. Also, a document summarizing the known and expected impacts of the European REACH regulation on the U.S. Department of Defence (DoD) by the Strategic Environmental Research and Development Program (SERDP) and Environmental Security Technology Certification Program (ESTCP) has stated that information on the propellants does not have to be registered or disclosed to ECHA[36]. More specifically, the referral was made in relation to the need for an Authorisation process, but it may also have implications to notifying substances in articles as producers and importers have

[36] Impact of European REACH Regulations on DoD and Military Equipment Manufacturers and Suppliers (2015): https://www.serdp-estcp.org/Program-Areas/Weapons-Systems-and-Platforms/Surface-Engineering-and-Structural-Materials/Impact-of-European-REACH-Regulations-on-DoD-and-Military-Equipment-Manufacturers-and-Suppliers

to notify to ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met:

- The substance is present in relevant articles above a concentration of 0.1 % w/w.
- The substance is present in relevant articles in quantities totalling over one tonne per year.

Background

Propellants are usually regarded as substances/mixtures within the context of the REACH Regulation and thus as such are not within the scope of this report. However, when they are as an integral part of an article (e.g. within an ammunition or artillery shell), they are regarded as part of the article. The ammunition cartridge containing the propellant is designed to launch a projectile and therefore the shape, surface and design of such ammunition cartridges determine their function to a greater degree than does its chemical composition[37].

Solid propellants are low-explosive with rapid or controlled burning[38] to produce gases to create the pressure to accelerate projectiles from guns or propel rockets toward targets (Folly and Mader, 2004). These types of propellants are often referred also as smokeless powders (e.g. Pichtel (2012)). DNT is used mostly in single-based or double-based solid propellants. Single-based powders contain nitrocellulose as the sole energetic material. According to Pichtel (2012), single base propellant has applications from small arms to cannons whereas double base propellants can have multiple applications.

Jenkins and Vogel (2014) did not list 2,4-DNT as an ingredient for double base propellants, and it seems that even if it can be found from this propellant type, it is not as often included in the principal ingredients as in single base propellants. Review of Pichtel (2012) lists 2,4-DNT in the composition of single and double based propellants. Common applications of 2,4-DNT containing propellants can be found in Table 11.

According to ECHA (2010) there are some literature referring to DNT in gunshot / post-blast residues (studies cited in Joshi et al. (2009)). Technical report (2010) refers to a study of Walsh et al. (2010) where it was shown how military training with artillery produces excess propellant that is burned on the training range and can result in point sources containing high concentrations of unreacted propellant constituents such as nitroglycerine and 2,4-DNT. Both are found at firing positions and propellant disposal areas.

Firing point or firing position residues are seen as a function of the efficiency of the weapon system and the composition of the propellant and especially larger weapon systems with longer barrels, rifled barrels or larger propellant loads consume propellants more efficiently whereas shorter barrels and smaller propellant loads leave relatively more residues (EPHW, 2019). Evidence of post-blast residues in the vicinity of the barrel (within meters) have been reported in the literature. 2,4-DNT is found embedded in fibrous propellant post-blast residues (Figure 2). A wipe sample of an artillery gun after shooting with 2,4-DNT containing propellant has shown 2,4-DNT residues, indicating a possibility for a particle deposition on the skin and the uniforms of artillery soldiers and their possible exposure through both dermal exposure and ingestion (Ampleman, 2009). Furthermore, handling of propellant bags and ammunition waste at the field, as well as burning excess propellant, are possible sources of human exposure.

[37] ECHA QA ID No 1059.
[38] Known as deflagration (Jenkins & Vogel, 2014).

2,4-DNT is mainly found on the topsoil layer where it accumulates (Walsh et al., 2011). Firing a large calibre gun also creates pressure waves that can mobilize dry soil effectively around the firing point which then can lead to repetitive airborne 2,4-DNT containing particles and possible further exposure. Therefore, overall levels and aggregation of 2,4-DNT in firing points may have significance for the military personnel practising regularly at these points.

Excess propellant is created while training due to the habit of adjusting the number of propellant bags of artillery for ballistic reasons (Walsh, 2016). Propellants utilized in artillery ammunition are added or removed inside the ammunition shell according to the desired firing power and radius. Loading or unloading the ammunition includes manual handling of the propellant bags at the field (Figure 3). In US and Canada it is common that this excess in burned at the training field (Walsh, 2016). Soil samples adjacent to burning points of propellants have contained up to 48 mg/kg of DNT (Hunt and Huntington, 1999) in Walsh (2016)). Walsh et al. (2010) tested for residues from burning the propellants on both bare ground and in specifically developed propellant burning pans. Remaining DNT residues when burning on wet and dry soil were 1.0 % and 0.95 %, respectively. When burning three different types of propellants in burning pans the fraction of DNT-residues ranged from <0.001 % to 0.020 % (Walsh et al., 2010).

Disposing the excess propellant at the field is a practise of unknown magnitude in the EU member states. However, the presence of excess propellant due training has been mentioned in recently published guidance report *Environmental Protection of Heavy Weapon Ranges: Technical and Practical Solutions* (EPHW, 2019). EPHW as a project was initiated by Finland and consisted of environmental and legal experts from the defence administrations of Finland, Sweden, Norway, Denmark, the United States and Canada. The report addresses 2,4-DNT contamination of soil in ranges, especially at firing points for mortars and howitzers. The levels of 2,4-DNT in soil at the training range are mentioned to be measurable but low, except in areas where excess propellant has been burned on the ground. According to the report, in these areas high concentrations of energetics such as 2,4-DNT may be found (EPHW, 2019).

The EPHW-report (2019) recommends a portable burn pan for excess artillery propellant disposal at the field as it facilitates the burning process and increases the burning efficiency, resulting in less dispersal of the energetics in the environment and less remaining unburned energetics. The burn pan is mentioned to be in use at three military bases in the US and that reports of its performance describing the technology are fully available. No experience of the use of the burning pan in Nordic countries involved in EPHW-working group is mentioned (EPHW, 2019).

The use of 2,4-DNT containing propellants may also lead to occupational exposure in military waste disposal and recycling facilities (Letzel et al., 2003).

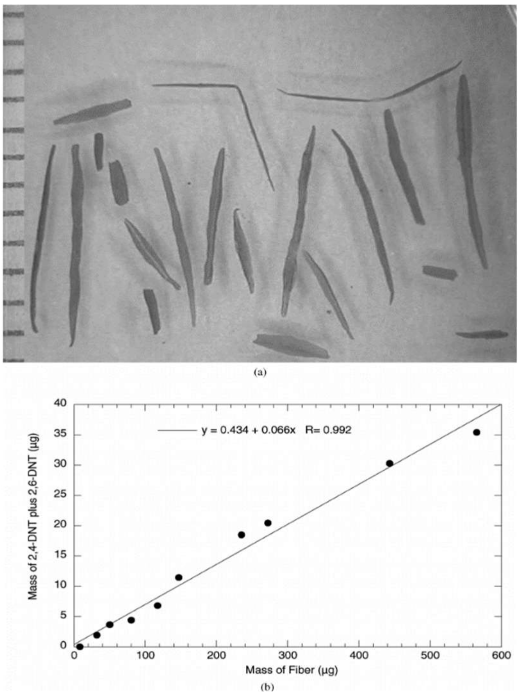

Figure 1: Single based propellant post-blast residues containing DNT (Source: Walsh et al., 2007).

Figure 2: Excess Propellant bags for artillery ammunition (Source: Poulin et al., 2011).

Annex 2: Discarded Exposure Scenario on risk from airbags to consumers (reproduced here for transparency reasons)

ES 3. Use in airbags and seat belt pre-tensioners

The amount of 2,4-DNT in this use is unknown. If we consider this through the sodium azide (NaN_3) a commonly used inflator in this application, a typical driver-side **airbag** contains approximately 50–80 g of NaN_3, with the larger passenger-side **airbag** containing about 250 g. Within about 40 milliseconds of impact, all these components react in three separate reactions that produce nitrogen gas. On average, there can be **seven airbags and five seat belts** in the car. The inflator is located in a closed system. The car manufacturer advices that potential exposure to consumers is minimal if the car has been maintained well. The inflator substance will be released only when there is a triggering factor i.e. crash event. The used amount of 2,4-DNT as an inflator in car-safety applications is unknown.

However, if the substance is used in these applications there will be releases to the interior air in case of a crash. For calculations, see Table 11.

Assuming that the amount of 2,4-DNT is comparable to sodium azide, another substance used for this purpose, then one pre-tensioner would contain 50 grams of 2,4-DNT. There could be 5 pre-tensioner capsules in a car. The total amount of 2,4-DNT would be in that case be 250 g in one car (only pre-tensioners). Residual amount of 2,4-DNT after incomplete burning is assumed to be 1250 mg (worst case scenario - 0.5 %). The air volume inside car is estimated to be 5 m^3. The systems are closed and there are no releases of 2,4-DNT in normal situation. However, in case of collapse, it is assumed that 10 and 30 % of the unburnt amount is released to the indoor air in car. A dilution factor of 2.5 is considered since there would be some air changes due to the possibility of broken windows or other damage.

The estimated concentration of 2,4-DNT inside the car is compared to the lowest national OEL (8 hour) in EU for 2,4-DNT and to the long-term DNEL for general population that the registrant has derived in his dossier for DNT. For general population, long-term DNEL is more suitable than acute DNEL since the substance is a carcinogen, even though the duration of the exposure situation is probably short. When the exposure estimates are compared to the long-term DNEL correction factors for very infrequent use (taken from ECETOC TRA Consumers modelling tool) can be used since the exposure situation will happen very rarely[39].

Conclusions

The estimated inhalation exposure to 2,4-DNT will be high compared to the lowest national OEL (8 hour) in EU for 2,4-DNT and to the long-term DNEL for general population if the car safety system (air bags or seat belt pretensioners) reacts and 2,4-DNT is released to the interior of the car and there are people in the car. The comparison with the OEL and using the DNEL already indicated risks to consumers, thus the Dossier

[39] For the calculations, a CSR provided for DNT registration dossier was utilised. Both limit values, OEL and DNEL, has been used since the DNEL derivation is not transparent in the dossier. The registrant has derived DNELs in their dossier, however the derivation process is not described comprehensively. It is described that the study is repeated dose study and the assessment factor is 50 and 25 for long-term and acute DNELs, respectively. However, the starting point value is not transparent. OELs are prepared by national experts and the values are very similar between countries.

Submitter is of the view that the risks are not adequately controlled as the substance in a non-threshold carcinogen.

The possibly exposed groups may contain, apart from the driver, also people and occupational groups attending accident sites often e.g. the police or fire personnel. Also, car repair technicians handling and replacing pre-tensioners and air bags may be at risk of exposure.

One consultation response was received from ACEA (#3526) informing that the amount of 2,4 DNT in seat belt pretensioners was on average 80mg. They assessed for 5 simultaneous seatbelt pretensioner deployments in a cabin, the concentration in the cabin would be 0.48ug/m^3. Therefore, this illustrative exposure scenario was removed from the report and replaced with a qualitative assessment.

Table 11: Discarded inhalation exposure from the use of 2,4-DNT in airbags and seat belt pre-tensioner. OEL-values for 8h and long term DNELs for DNT, respectively.

	DNT	Unburnt DNT	Unburnt and deposit	Release to air	Volume in car interior*	Dilution factor**	Adjust. factor for very infrequent exposure	Conc. in car interior	OEL (8 h)***	OEL-based RCR	DNEL long-term****	DNEL-based RCR
	g	%	mg	%	m^3			mg/m^3	mg/m^3		mg/m^3	
One air bag/seat belt pretensioner	50	0.50	250	10	5	2.5	0.01	0.02	0.15	0.1	0.009	2.2
One air bag/seat belt pretensioner	50	0.50	250	30	5	2.5	0.01	0.06	0.15	0.4	0.009	6.7
Five air bags/seat belt	250	0.50	1250	10	5	2.5	0.01	0.10	0.15	0.7	0.009	11.1
Five air bags/seat belt	250	0.50	1250	30	5	2.5	0.01	0.30	0.15	2.0	0.009	33.3

* It is assumed that the air volume inside the car is $5m^3$, in case of windows breaking/other damage allowing air in; **Dilution factor is a factor for air volume changes outdoor/indoor, the value is from ECETOC TRA Consumers V.3.1; Five countries in Europe have an OEL for 2,4-DNT; *** The range for the national OELs 0.15-1.0 mg/m^3 (8 h), for 15 minutes there is only 0.3 mg/m^3;**** Long-term DNEL is derived by the registrant.