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Research article

SCIENTIFIC SUBSTANTIATION OF AVERAGE ANNUAL MAXIMUM PERMISSIBLE LEVEL OF VANADIUM PENTOXIDE IN AMBIENT AIR AS PER PERMISSIBLE HEALTH RISK

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Relevance of this study is determined by the sanitary-epidemiological legislation of the Russian Federation with stipulated requirements to create hygiene standards for environmental factors ensuring their safety for people. These hygienic standards should guarantee absence of impermissible lifetime health risks.

Divanadium pentoxide is a chemical that should be mandatorily regulated in ambient air under long-term exposure due to its wide prevalence and high toxicity.

An average annual MPL for divanadium pentoxide was established by using systemic analysis of research literature and regulatory documents. According to selection results, three key epidemiological studies were taken for further analysis. They provided evidence of adverse effects produced by divanadium pentoxide on human health (the respiratory organs in particular) under chronic inhalation exposure.

When analyzing a study design, we paid special attention to description of observation groups, values of exposure and nature of its effects, adverse health outcomes caused by exposure to divanadium pentoxide as well as to a type and a value of a point of departure. We calculated a value of the total (complex) uncertainty factor in order to establish an average annual maximum permissible level of the analyzed chemical.

As a result, we suggest a scientifically substantiated (among other things, as per permissible health risk levels) average annual maximum permissible level for divanadium pentoxide, which equals 0.0001 mg/m^3. This level is safe for human health under lifetime exposure. It is noteworthy that this level corresponds to 'low uncertainty', which indicates its high safety for human health.

Keywords: *average annual MPL, divanadium pentoxide, ambient air, risk indicators, scientific substantiation, hygiene standard, environmental factors, uncertainty factor.*

Legal grounds for establishing safe levels of chemicals in ambient air are fixed by the RF Federal Law issued on March 30, 1990 No. 52-FZ On Sanitary-Epidemiological Wellbeing of the Population. It stipulates general principles and fundamentals of the state policy in the sphere of providing sanitary-epidemiological wellbeing of the population, in particular, sanitary-epidemiological requirements to ambient air[1]. According to the 52-FZ, maximum permissible levels in ambient air serve as indicators describing safety for human life and health and are determined in conformity with the valid sanitary rules and

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[1] O sanitarno-epidemiologicheskom blagopoluchii naseleniya: Federal'nyi zakon ot 30.03.1999 № 52-FZ (poslednyaya redaktsiya) [On Sanitary-Epidemiological Wellbeing of the Population: the federal Law issued on March 30, 1999 No. 52-FZ (the latest edition)]. *Konsultant Plus*. Available at: http://www.consultant.ru/document/cons_doc_LAW_22481/ (November 30, 2023) (in Russian).

norms (SanPiN 1.2.3685-21 Hygienic Standards and Requirements to Providing Safety and (or) Harmlessness of Environmental Factors for People[2]). Development of sanitary rules involves establishing requirements to prevent harmful environmental factors from affecting human health. This includes identifying those conditions, which give grounds for calculating and assessing health risks[1]. This implies that a safe standard describes an environmental factor as regards its lifetime safety for humans[1] as absence of any impermissible health risks. Given that, it is advisable to substantiate average annual maximum permissible levels (MPLav.an.) relying on a permissible health risk as a key criterion.

Relevance of examining divanadium pentoxide is determined by volumes of the chemical emitted into ambient air by industries. According to Rosprirodnadzor data (the Form 2-TP), approximately 150 tons of divanadium pentoxide are annually emitted into ambient air[3]. Over 2011–2018, an average volume of divanadium pentoxide emitted into ambient air equaled 328 tons[4].

Industry is a universally recognized major source of ambient air pollution (56 % of all pollution types); metallurgy accounts for 23 % in overall industrial pollution. Divanadium pentoxide is mostly emitted into ambient air by ferrous metallurgy (95 %). Divanadium pentoxide is most often used as a dopant to make wearproof, heatproof and corrosion-proof alloys (primarily, some specific steels). As of 2019, Russia took the 5th place in the world as a steel producer with the total steel output being 71.6 million tons per year.

At present, more than 1.5 thousand ferrous metallurgic productions operate in the Russian Federation. Seventy percent of them are city-forming enterprises and this means that people who live in such monotowns are exposed to airborne divanadium pentoxide. The largest ferrous metallurgy plants are located in the Urals (31.1 %), Siberian (18.5 %), Central (17.6 %) and Volga (14.5 %) Federal Districts.

An average working period of a metallurgy plant in Russia is established to exceed 140 years (exemplified by 30 largest ones). Still, metallurgic production continues to develop and this is the reason for a long-term exposure to divanadium pentoxide, likely, a lifetime one.

Relevance of regulating levels of divanadium pentoxide arises due to its high toxicity, which is determined by several adverse effects occurring under inhalation exposure. Divanadium pentoxide is considered to primarily affect the respiratory organs [1–10]. However, hazard identification performed in some studies established adverse effects produced by divanadium pentoxide on other organs and systems, for example, eyes[5] [11–15], skin [11], and the immune system as dysfunction of its humoral and cellular components [6, 16, 17]. According to the Federal Register of Potentially Hazardous Chemicals and Biological Agents, negative health outcomes can also occur in the central nervous system, cardiovascular system, gastrointestinal tract, liver, kidneys, adrenals, spleen, teeth, and bone tissue;

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[2] Ob utverzhdenii sanitarnykh pravil i norm SanPiN 1.2.3685-21 «Gigienicheskie normativy i trebovaniya k obespecheniyu bezopasnosti i (ili) bezvrednosti dlya cheloveka faktorov sredy obitaniya»: Postanovlenie glavnogo gosudarstvennogo sanitarnogo vracha Rossiiskoi Federatsii ot 28.01.2021 № 2 (s izmeneniyami na 30 dekabrya 2022 goda) [On Approval of the sanitary rules and norms SanPiN 1.2.3685-21 Hygienic Standards and Requirements to Providing Safety and (or) Harmlessness of Environmental Factors for People: the Order by the RF Chief Sanitary Inspector dated January 28, 2021 No. 2 (last edited on December 30, 2022)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/573500115 (November 30, 2023) (in Russian).

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changes in peripheral blood and metabolic disorders are also possible[6].

The foregoing determined **the aim of this study,** which was to substantiate the maximum permissible level of divanadium pentoxide in ambient air as per permissible health risks under long-term exposure.

Materials and methods. Literature sources were selected by systemic analysis with emphasis on those investigating occurrence of negative health outcomes under chronic inhalation exposure to divanadium pentoxide. Our research covered more than 100 foreign and Russian works including articles, reports and reviews as well as regulatory and substantiating documents.

Several criteria were used to include materials into further analysis: a full text of an article available in open access; an article containing quantitative indicators that describe an analyzed dependence – response model; available data on a level of exposure to divanadium pentoxide and detailed description of a study design.

Next, we selected key studies most relevant for establishing an average annual maximum permissible level (MPLav.an.) of divanadium pentoxide.

Methodical approaches applied in this work to identify a study that could provide a solid ground for substantiating MPLav.an. as well as an algorithm for substantiating it have been described in detail in research literature[7].

Uncertainty of an average annual MPL was established by estimating indicators that were critical and considered any interspecies and / or intraspecies extrapolation; exposure mode applied in a study (manageable or real world conditions, acute / subchronic / chronic exposure); choice on a point of departure and initial data volume.

The ultimate uncertainty was identified based on three most significant indicators in accordance with semi-quantitative criteria provided in Table 1.

Table 1

Criteria to describe correspondence of safe standard uncertainty

Criterion	Uncertainty
Below 300	Low uncertainty
Between 301 and 600	Medium uncertainty
Between 601 and 1000	High uncertainty

Results and discussion. According to selection results, three key epidemiological studies were taken for further analysis:

– an epidemiological study by G.B. Irsigler et al. with its focus on effects produced by divanadium pentoxide under subchronic inhalation exposure (South Africa) [8];

– an epidemiological study by M. Kiviluoto on effects of divanadium pentoxide under chronic inhalation exposure produced on workers employed at divanadium pentoxide production in Finland [18–20];

– an epidemiological study by C.E. Lewis on effects produced by divanadium pentoxide on workers at vanadium productions in the USA under subchronic inhalation exposure [3].

Analysis of a level able to cause a negative health outcome allowed establishing a point of departure for MPLav.an. substantiation. The lowest exposure that causes an adverse effect (LOAEL) was taken as this point of departure in all analyzed studies.

Critical points and corresponding values of modifying factors were established relying on analysis of a study design. Detailed description of study designs is provided in Table 2.

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Table 2

Description of key study designs used to establish average annual MPL of divanadium pentoxide

Parameter	G.B. Irsigler, et al. (1999)	M. Kiviluoto (1979–1981)	C.E. Lewis (1959)
Study	Epidemiological	Epidemiological	Epidemiological
Study type	Case – control	Case – control	Case – control
Case	12 workers employed at vanadium production (South Africa)	63 workers employed at divanadium pentoxide production, average work records equal to 11 years (Finland)	24 workers employed at vanadium production (USA)
Sensitivity of a case group	Workers	Workers	Workers
Control	12 workers employed at vanadium production but not exposed to divanadium pentoxide	22 mine operators not exposed to divanadium pentoxide	45 workers not exposed to divanadium pentoxide, comparable as per age and socioeconomic status
Exposure type	Inhalation	Inhalation	Inhalation
Characteristics of exposure	Subchronic exposure (6 months)	Chronic exposure (260 air samples taken in the breathing zone between 1970 and 1976)	Subchronic exposure (6 months)
Exposure level, mg/m^3	Between 0.15 and 1.53	Between 0.018 and 0.89	Between 0.097 and 0.243 (Colorado) Between 0.018 and 0.925 (Ohio)
Negative outcomes	Bronchial hyperreaction	Elevated levels of neutrophils and plasmatic cells in nasal duct mucosa	Cough, mucus, irritated eye, throat and nose mucosa, nose bleeding, hoarseness
Critical organ / system corresponding to negative health outcomes	Respiratory organs	Respiratory organs	Respiratory organs
Point of departure	LOAEL = 0.015 mg/m^3	LOAEL = 0.018 mg/m^3	LOAEL = 0.018 mg/m^3

All analyzed studies were case – control ones and were performed on workers employed at divanadium pentoxide production. This makes it possible to reduce levels of uncertainty and modifying factors as much as possible considering interspecies variations but simultaneously to increase a level of a factor responsible for intraspecies variations.

In all analyzed studies, LOAEL for respiratory dysfunction is taken as the point of departure. This fact confirms findings of most studies focusing on effects produced by divanadium pentoxide on human health and provides solid evidence that it is the respiratory system that first reacts to them and is a target one in this respect.

At the same time, certain differences were established in profound examination of a level, which brought about negative changes. Thus, for example, M. Kiviluoto reports preclinical laboratory disorders in his study such as authentic quantitative changes in cellular components in tissues, which indicates earlier signs of negative effects produced by divanadium on the body. But effects described by G.B. Irsigler et al. and C.E. Lewis manifested themselves as non-specific clinical symptoms such as cough, mucus, etc. Identification of negative outcomes at a lower organizational level was a priority factor in selecting a key study as regards this parameter.

Analysis of exposure load revealed that divanadium pentoxide affected the body by inhalation in all key studies. However, inhalation exposure was subchronic in the studies by G.B. Irsigler et al. and C.E. Lewis and lasted

6 months and only M. Kiviluoto described chronic exposure (between 1970 and 1976); average working records in the branch equaled 11 years and air samples (260 samples were taken overall, 64 in 1970–1975 and 196 in 1976) were taken in the breathing zone. In this case, a key study for establishing an average annual MPL is the one describing longer exposure.

Exposures identified for workers in all three studies were given as ranges of concentrations. All three studies report that any level within those ranges can have negative effects on human health. Bearing in mind that the analyzed studies were epidemiological and, consequently, an exposure mode was not manageable as regards a dose per one person, it seems impossible to establish an exact concentration that caused negative health outcomes. This is an uncertainty of this study.

However, researchers took a minimal level reported in their studies as LOAEL. The lowest LOAEL of divanadium pentoxide in the breathing zone was detected in the study by G.B. Irsigler et al., 0.015 mg/m^3. In two other studies (M. Kiviluoto and C.E. Lewis), the lowest exposure was fixed at the same level, 0.018 mg/m^3.

Control groups were comparable with cases in all there analyzed studies.

We identified values of modifying factors for each critical point relying on the results obtained by analyzing design of the key studies. Table 3 provides semi-quantitative assessment of modifying factors for each study.

Depending on a study, several modifying factors are the most significant for establishing a safe level of divanadium pentoxide. They consider sensitivity of a group under exposure, an exposure mode as regards real world conditions, a type of a point of departure and exposure duration.

The interspecies extrapolation factor and the factor that considers an initial data volume were minimal in all studies and equaled one.

We used the total (complex) uncertainty factor in our calculations, which equaled 180 in all studies (since it is advisable to use not more than three modifying factors). Given that, we established values recommended for use as an average annual MPL of divanadium pentoxide, which are 0.0008 mg/m^3 and 0.0001 mg/m^3. The latter value of 0.0001 mg/m^3 was established relying on findings of two studies (M. Kiviluoto and C.E. Lewis).

Since the safe standardization principle states that a limiting indicator should be used, we recommend using a value of 0.0001 mg/m^3 as an average annual MPL of divanadium pentoxide.

Results obtained by calculating total uncertainty revealed that the established safe level corresponded to ‘low uncertainty’, which means its high safety for human health.

Table 3

Modifying factors for critical research points*

Modifying factor	G.B. Irsigler et al., 1999	M. Kiviluoto, 1979–1981	C.E. Lewis, 1959
Interspecies extrapolation factor	1	1	1
Intraspecies extrapolation factor	**10**	**10**	**10**
Factor of extrapolation from manageable exposure to real world conditions	3	**3**	3
Factor that considers a type of a point of departure	**6**	**6**	**6**
Factor that considers a volume of initial data	1	1	1
Extrapolation of exposure duration	**3**	1	**3**
Total (complex) uncertainty factor	**180**	**180**	**180**

Note: * indicators that were considered in calculating the total (complex) uncertainty factor are given in bold.

At present, there is evidence, that a level of divanadium pentoxide that equals 0.0001 mg/m^3 is safe for humans. For example, minimum risk levels (MRLs) for vanadium compounds were established at the same level by the Agency for Toxic Substances and Disease Registry (ATSDR) of the US State Department of Health and Human Services. Substantiation materials report that identification of these levels was based on a toxicological study performed on F344 rats [16]. It established several negative health outcomes such as dysfunctions of some respiratory organs (lung tissues, the larynx and nasal cavity) under chronic exposure to 0.05 mg/m^3 of divanadium pentoxide. When establishing MRL, ATSDR experts used calculation methods and software for mathematic modeling. They established MRL of divanadium pentoxide to equal 0.0001 mg/m^3 based on a level equivalent for humans ($BMCL_{HEC}$) calculated with use of modifying factors, which amounted to 10 and 3 in their quantitative equivalent.

The key study for establishing a safe standard was the one by M. Kiviluoto, although the same results were obtained relying on two independent studies in our research on substantiating an average annual MPL for divanadium pentoxide. This is easily explained by the fact that negative health outcomes in the respiratory system were identified at the cellular level in the study by M. Kiviluoto, which is lower than in the study by C.E. Lewis. In addition to that, the volume of initial data was also larger, more air samples were analyzed and the case group included more people.

The substantiated average annual MPL of divanadium pentoxide is equal to its reference concentration (RfC) under chronic inhalation exposure[8]. This allows us to conclude that the average annual MPL equal to 0.0001 mg/m^3 corresponds to permissible risk for human health.

Conclusion. Therefore, the findings reported in the epidemiological study by M. Kiviluoto were used as substantiation of the average annual maximum permissible level of divanadium pentoxide. LOAEL equal to 0.018 mg/m^3 of divanadium pentoxide was taken as the point of departure since this dose was able to cause negative health outcomes in the respiratory organs. The total modifying factor equal to 180 was used in calculating a safe standard for the chemical.

The established average annual maximum permissible level in ambient air equals 0.0001 mg/m^3. This level has been substantiated relying on permissible levels of health risks and therefore it ensures lifetime safety for human health.

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