

SUBSIDIARY LEGISLATION 424.22

PROTECTION OF WORKERS FROM THE RISKS RELATED TO EXPOSURE TO CARCINOGENS, MUTAGENS OR REPROTOXIC SUBSTANCES AT WORK REGULATIONS*

Substituted by:
L.N. 102 of 2024.

16th May, 2003

*LEGAL NOTICE 122 of 2003, as amended by Legal Notice 197 of 2015 ,
318 of 2019, 51 of 2021 and 102 of 2024 and Act XXXIII of 2024.*

1. (1) The title of these regulations is the Protection of Workers from the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances at Work Regulations.

Citation, scope and
application.
Amended by:
L.N. 318 of 2019;
L.N. 51 of 2021;
L.N. 102 of 2024.

(2) These regulations have as their objective the protection of workers against risks to their health and safety, arising from or are likely to result from exposure to carcinogens, mutagens or reprotoxic substances at the workplace, including prevention of such risks.

(3) These regulations shall apply to activities in which workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances as a result of their work.

(4) As regards asbestos, insofar as any provisions in these regulations are more favourable to safety and health at work than any other provision contained in regulations dealing with asbestos, these regulations shall apply.

(5) These regulations shall not apply to workers exposed only to radiation insofar as such issue is regulated under any other regulation or legislative provision.

(6) The purpose of these regulations is to transpose:

- (a) 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, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC); and
- (b) Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures; and
- (c) Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers

*These regulations have been transferred to Cap. 646. Vide S.L. 646.14 and Act XXXIII of 2024.

from the risks related to exposure to carcinogens or mutagens at work; and

- (d) Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Council Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; and
- (e) Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; and
- (f) Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Interpretation.
Amended by:
L.N. 197 of 2015;
L.N. 102 of 2024.
XXXIII.2024.
First Schedule.
Cap. 646.

2. In these regulations, unless the context otherwise requires:

"Act" means the Health and Safety at Work Act;

"Authority" means the Occupational Health and Safety Authority established by article 8 of the Act;

"biological limit value" means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect

"carcinogen" means:

- (a) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council;
- (b) *(deleted by L.N. 197 of 2015)*;
- (ba) "reprotoxic substance" means a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;
- (bb) "non-threshold reprotoxic substance" means a reprotoxic substance to which there is no safe level of exposure for workers' health and which is identified as such in the notation column of Schedule III;
- (bc) "threshold reprotoxic substance" means a reprotoxic substance for which a safe level of exposure exists below which there is no risk to workers' health and which is identified as such in the notation column of Schedule III;
- (c) a substance, preparation or process referred to in

Annex I as well as a substance or preparation released by a process referred to in Annex I;

"doctor" means a medical practitioner, specialised in internal or oncological medicine, who is appointed by an employer to examine workers exposed to carcinogens or mutagens;

"health surveillance" means the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific carcinogens, mutagens or reprotoxic substances at work.

"limit value" means, unless otherwise specified, the limit of the time-weighted average of the concentration for a carcinogen, mutagen or reprotoxic substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Schedule III;

"mutagen" means:

- (a) a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council;
- (b) *(deleted by L.N. 197 of 2015).*

3. (1) In the case of any activity likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens or reprotoxic substances. The employer must supply the Authority at its request with the information used for making the assessment.

Determination of risks.
Amended by:
L.N. 102 of 2024.

(2) When assessing the risk, account shall be taken of all other routes of exposure, such as absorption into and, or through the skin.

(3) When the risk assessment is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at particular risk and shall, *inter alia*, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens, mutagens or reprotoxic substances.

4. (1) The employer shall reduce the use of a carcinogen, mutagen or reprotoxic substance at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.

Reduction and replacement.
Amended by:
L.N. 197 of 2015;
L.N. 102 of 2024.

(2) The employer shall, upon request, submit the findings of his investigations to the Authority.

Prevention and
reduction of
exposure.

Amended by:
L.N. 197 of 2015;
L.N. 102 of 2024.

5. (1) Where the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, workers' exposure must be prevented.

(2) Where it is not technically possible to replace the carcinogen, mutagen or reprotoxic substance by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen, mutagen or reprotoxic substance is, in so far as is technically possible, manufactured and used in a closed system.

(3) Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers to the carcinogen, mutagen or non-threshold reprotoxic substance is reduced to as low a level as is technically possible.

(3A) Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer shall ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is reduced to a minimum.

(3B) The employer shall, with regard to reprotoxic substances other than non-threshold reprotoxic substances and threshold reprotoxic substances, apply sub-regulation (3A). In such a case, when carrying out the risk assessment referred to in regulation 3, the employer shall duly take into account the possibility that a safe level of exposure for workers' health for such a reprotoxic substance might not exist and shall lay down appropriate measures in that regard.

(4) Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Schedule III.

(5) Wherever a carcinogen, mutagen or reprotoxic substance is used, the employer shall apply all the following measures:

- (a) limitation of the quantities of a carcinogen, mutagen or reprotoxic substance at the place of work;
- (b) keeping as low as possible the number of workers exposed or likely to be exposed;
- (c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens or reprotoxic substances into the place of work;
- (d) evacuation of carcinogens, mutagens or reprotoxic substances at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
- (e) use of existing appropriate procedures for the measurement of carcinogens, mutagens or reprotoxic substances, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
- (f) application of suitable working procedures and

methods;

- (g) collective protection measures and, or, where exposure may not be avoided by other means, individual protection measures;
- (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
- (i) information for workers;
- (j) demarcation of risk areas and use of adequate warning and safety signs including "no smoking" signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens or reprotoxic substances;
- (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
- (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;
- (m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

6. Where the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, an employer shall, when requested, make available to the Authority appropriate information on:

Information for the
Authority.
Amended by:
L.N. 197 of 2015;
L.N. 102 of 2024.

- (a) the activities and, or industrial processes carried out, including the reasons for which carcinogens, mutagens or reprotoxic substances are used;
- (b) the quantities of substances or mixtures manufactured or used which contain carcinogens, mutagens or reprotoxic substances;
- (c) the number of workers exposed;
- (d) the preventive measures taken;
- (e) the type of protective equipment used;
- (f) the nature and degree of exposure;
- (g) the cases of replacement.

7. (1) In the event of an unforeseeable event or an accident which is likely to result in an abnormal exposure of workers, the employer shall inform the workers thereof.

Unforeseen
exposure.

(2) Until the situation has been restored to normal and the causes of the abnormal exposure have been eliminated:

- (a) only those workers who are essential to the carrying out of repairs and other necessary work shall be permitted to work in the affected area;
- (b) the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear; the

exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker;

- (c) unprotected workers shall not be allowed to work in the affected area.

Foreseeable exposure.

8. (1) For certain activities such as maintenance, in respect of which it is foreseeable that there is the potential for a significant increase in exposure of workers, and in respect of which all scope for further technical preventive measures for limiting workers' exposure has already been exhausted, the employer shall determine, after consultation of the workers and, or their representatives in the undertaking or establishment, without prejudice to the employer's responsibility, the measures necessary to reduce the duration of workers' exposure to the minimum possible and to ensure protection of workers while they are engaged in such activities.

(2) Pursuant to subregulation (1), the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear as long as the abnormal exposure persists; that exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker.

(3) Appropriate measures shall be taken to ensure that the areas in which the activities referred to in subregulation (1) take place are clearly demarcated and indicated or that unauthorized persons are prevented by other means from having access to such areas.

Access to risk areas.

9. Appropriate measures shall be taken by employers to ensure that access to areas in which the activities in respect of which the results of the assessment referred to in regulation 3 reveal a risk to workers' safety or health take place are accessible solely to workers who, by reason of their work or duties, are required to enter them.

Personal hygiene and individual protection.
Amended by:
L.N. 102 of 2024.

10. (1) Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, mutagens or reprotoxic substances, to take appropriate measures to ensure that::

- (a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances;
- (b) workers are provided with appropriate protective clothing or other appropriate special clothing;
- (c) separate storage places are provided for working or protective clothing and for street clothes;
- (d) workers are provided with appropriate and adequate washing and toilet facilities;
- (e) protective equipment is properly stored in a well-defined place; it is checked and cleaned if possible before, and in any case after each use; defective equipment is repaired or replaced before further use.

- (2) Workers may not be charged for the cost of these measures.

11. (1) Appropriate measures shall be taken by the employer to ensure that workers and, or workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

Information and training of workers.
Amended by:
L.N. 102 of 2024.

- (a) potential risks to health, including the additional risks due to tobacco consumption;
- (b) precautions to be taken to prevent exposure;
- (c) hygiene requirements;
- (d) wearing and use of protective equipment and clothing;
- (e) steps to be taken by workers, including rescue workers, in the case of incidents and to prevent incidents.

The training shall be:

- (i) adapted to take account of new or changed risk, in particular when workers are or likely to be exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including those contained in hazardous medicinal products, or in case of changing circumstances related to work,
- (ii) provided periodically in healthcare settings to all workers who are exposed to carcinogens, mutagens or reprotoxic substances, in particular where new hazardous medicinal products containing those substances are used, and
- (iii) repeated periodically in other settings if necessary.

(2) Employers shall inform workers of installations and related containers containing carcinogens, mutagens or reprotoxic substances, ensure that all containers, packages and installations containing carcinogens, mutagens or reprotoxic substances are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Where a biological limit value has been set out in Schedule IV, health surveillance shall be mandatory for working with the carcinogen, mutagen or reprotoxic substance in question, in accordance with the procedures laid down in that Schedule. Workers shall be informed of that requirement before being assigned to the task involving the risk of exposure to the carcinogen, mutagen or reprotoxic substance indicated.

12. Appropriate measures shall be taken to ensure that:

Information for workers.

- (a) workers and, or any workers' representatives in the undertaking or establishment can check that these regulations are applied or can be involved in its application, in particular with regard to:
 - (i) the consequences for workers' safety and health

of the selection, wearing and use of protective clothing and equipment, without prejudice to the employer's responsibility for determining the effectiveness of protective clothing and equipment;

- (ii) the measures determined by the employer which are referred to in regulation 8(1), without prejudice to the employer's responsibility for determining such measures;
- (b) workers and, or any workers' representatives in the undertaking or establishment are informed as quickly as possible of abnormal exposures, including those referred to in regulation 8, of the causes thereof and of the measures taken or to be taken to rectify the situation;
- (c) the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, indicating, if the information is available, the exposure to which they have been subjected;
- (d) the doctor and, or the Authority as well as all other persons who have responsibility for health and safety at work at the employer's workplace have access to the list referred to in paragraph (c);
- (e) each worker has access to the information on the list which relates to him personally;
- (f) workers and, or any workers' representatives in the undertaking or establishment have access to anonymous collective information.

Consultation and participation of workers.

13. (1) Employers shall consult workers and, or their representatives and allow them to take part in discussions on all questions relating to safety and health at work. This presupposes:

- the consultation of workers,
- the right of workers and, or their representatives to make proposals,
- balanced participation in accordance with the General Provisions for Health and Safety at Work Places Regulations.

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(2) Workers or workers' representatives with specific responsibility for the safety and health of workers shall take part in a balanced way, in accordance with applicable laws and, or practices, and shall be consulted in advance and in good time by the employer with regard to:

- (a) any measure which may substantially affect safety and health;
- (b) the designation of worker or workers which the

employer is obliged to designate to carry out activities related to the protection and prevention of occupational risks for the undertaking and, or establishment and the workers which the employer is obliged to designate to implement measures *inter alia*, for first aid, fire-fighting and the evacuation of workers, and the activities related to the protection and prevention of occupational risks;

- (c) the following information:
 - (i) an assessment of the risks to safety and health at work, including those facing groups of workers exposed to particular risks;
 - (ii) the protective measures to be taken and, if necessary, the protective equipment to be used;
 - (iii) a list of occupational accidents resulting in a worker being unfit for work for more than three working days;
 - (iv) reports on occupational accidents suffered by his workers;
 - (v) the safety and health risks and protective and preventive measures and activities in respect of both the undertaking and, or establishment in general and each type of workstation and, or job;
 - (vi) the measures taken in relation to first aid, fire-fighting and the evacuation of workers;
 - (vii) the appropriate measures taken so that employers of workers from any outside undertakings and, or establishments engaged in work in his undertaking and, or establishment receive adequate information concerning the points referred to in subparagraphs (v) and (vi);
 - (viii) the appropriate measures taken so that workers with specific functions in protecting the safety and health of workers, or workers' representatives with specific responsibility for the safety and health of workers may be able to have access, to carry out their functions and to:
 - the risk assessment and protective measures referred to in subparagraphs (v) and (vi);
 - the list and reports referred to in subparagraphs (iii) and (iv);
 - the information yielded by protective and preventive measures, inspection agencies and bodies responsible for safety and health;
- (d) the enlistment, where appropriate, of the competent services or persons outside the undertaking and, or establishment, where such protective and preventive measures cannot be organized for lack of competent personnel in the undertaking and, or establishment;

- (e) the planning and organization of the training to each worker regarding adequate safety and health training, in particular in the form of information and instructions specific to his workstation or job:

- on recruitment,
- in the event of a transfer or a change of job,
- in the event of the introduction of new work equipment or a change in equipment,
- in the event of the introduction of any new technology.

(3) Workers' representatives with specific responsibility for the safety and health of workers shall have the right to ask the employer to take appropriate measures and to submit proposals to him to that end to mitigate hazards for workers and, or to remove sources of danger.

(4) The workers referred to in subregulation (2) and the workers' representatives referred to in subregulations (2) and (3) may not be placed at a disadvantage because of their respective activities referred to in subregulations (2) and (3).

(5) Employers must allow workers' representatives with specific responsibility for the safety and health of workers adequate time off work, without loss of pay, and provide them with the necessary means to enable such representatives to exercise their rights and functions.

(6) Workers and, or their representatives are entitled to appeal to the Authority if they consider that the measures taken and the means employed by the employer are inadequate for the purposes of ensuring safety and health at work. Workers' representatives must be given the opportunity to submit their observations during inspection visits by the Authority.

Health
surveillance.
Amended by:
L.N. 318 of 2019;
L.N. 102 of 2024.

14. (1) The employer shall make arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in regulation 3 reveal a risk to health or safety. The doctor or Authority may indicate that health surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned.

- (2) (a) The arrangements referred to in subregulation (1) shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:

- prior to exposure,
- at regular intervals thereafter.

- (b) Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

(3) If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, mutagens or reprotoxic substances, or if a biological limit value is found to have

been exceeded, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

(4) In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers. Biological monitoring and related requirements may form part of health surveillance.

(5) Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

(6) Workers shall have access to the results of the health surveillance which concern them, and the workers concerned or the employer may request a review of the results of the health surveillance.

(7) Practical recommendations for the health surveillance of workers are given in Schedule II.

(8) All cases of cancer, adverse effects on sexual function and fertility in adult male and female workers or developmental toxicity in their offspring identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen, mutagen or reprotoxic substance shall be notified to the competent authority.

15. (1) With regard to carcinogens and mutagens, the list referred to in paragraph (c) of regulation 12, and the medical record referred to in regulation 14(4) shall be kept for at least forty (40) years following the end of exposure, in accordance with national law or practice.

Record keeping.
Amended by:
L.N. 102 of 2024.

(1A) With regard to reprotoxic substances, the list referred to in paragraph (c) of regulation 12, and the medical record referred to in regulation 14(4) shall be kept for at least five (5) years following the end of exposure, in accordance with national law or practice.

(2) Those documents shall be made available to the Authority in cases where the undertaking ceases activity.

16. Limit values and other directly related provisions are set out in Schedule III.

Limit values.

17. In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement to do something, or to do something so far as is reasonably practicable, it shall be for the accused to prove (as the case may be) that it was not practicable or not reasonably practicable to do more than was in fact done to satisfy the duty or requirement, or that there was no better practicable means than was in fact used to satisfy the duty or requirement.

Onus of proof.

18. Any person who knowingly or recklessly interferes with the process of providing a safe and healthy place of work, shall be guilty of an offence.

Offences.

*Amended by:
L.N. 197 of 2015;
L.N. 318 of 2019.*

SCHEDULE I
[Regulation 2(c)]

List of substances, mixtures and processes

1. Manufacture of auramine.
2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soots, coal tar or coal pitch.
3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
4. Strong acid process in the manufacture of isopropyl alcohol.
5. Work involving exposure to hardwood dust.
6. Work involving exposure to respirable crystalline silica dust generated by work process

*Amended by:
L.N. 102 of 2024.*

SCHEDULE II
(Regulation 14 (7))

Practical recommendations for the health surveillance of workers

1. The doctor and, or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens or reprotoxic substances shall be familiar with the exposure conditions or circumstances of each worker.
2. Health monitoring of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:
 - keeping records of a worker's medical and occupational history,
 - a personal interview,
 - where appropriate, biological monitoring, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health monitoring, in the light of the most recent knowledge available to occupational medicine.

Amended by:
L.N. 197 of 2015;
L.N. 318 of 2019.
Substituted by:
L.N. 51 of 2021;
L.N. 102 of 2024.

SCHEDULE III
(Regulation 16)
Limit values and other directly related provisions
Limit values for occupational exposure

Name of agent	EC No (¹)	CAS No (²)	Limit values						Notation	Transitional measures
			8 hours (³)			Short-term (⁴)				
			mg/m ³ (⁵)	ppm (⁶)	f/ml (⁷)	mg/ m3 (⁵)	ppm (⁶)	f/ml (⁷)		
Hardwood dusts	-	-	2 (⁸)	-	-	-	-	-	-	Limit value: 3 mg/m3 until 17 January 2023
Chromium (VI) compounds which are car- cinogens within the meaning of paragraph (a) of the defenition "carcinogen" in regulation 2 (as chromium)	-	-	0.005	-	-	-	-	-	-	Limit value: 0.010 mg/m3 until 17 Janu- ary 2025 Limit value: 0.025 mg/m3 for welding or plasma cutting pro- cesses or sim- ilar work processes that generate fume until 17 January 2025
Refractory ceramic fibres which are car- cinogens within the meaning of paragraph (a) of definition "car- cinogen" in reg- ulation 2	-	-	-	-	0.3	-	-	-	-	-
Respirable crys- talline silica dust	-	-	0.1 (⁹)	-	-	-	-	-	-	-

Benzene	200-753-7	71-43-2	0.66	0.2	-	-	-	-	skin (10)	Limit value of 1ppm (3.25 mg/m ³) until 5 April 2024. Limit value of 0,5 ppm (1.65 mg/m ³) from 5 April 2024 until 5 April 2026.
Vinyl chloride monomer	200-831-0	75-01-4	2.6	1	-	-	-	-	-	-
Ethylene oxide	200-849-9	75-21-8	1.8	1	-	-	-	-	skin (10)	-
1,2- Epoxyp propane	200-879-2	75-56-9	2.4	1	-	-	-	-	-	-
Trichloroethylene	201-167-4	79-01-6	54.7	10	-	164.30	1	-	skin (10)	-
Acrylamide	201-173-7	79-06-1	0.1	-	-	-	-	-	skin (10)	-
2-Nitropropane	201-209-1	79-46-9	18	5	-	-	-	-	-	-
o-Toluidine	202-429-0	95-53-4	0.5	0.1	-	-	-	-	skin (10)	-
4,4'-Methylene-dianiline	202-974-4	101-77-9	0.08	-	-	-	-	-	skin (10)	-
Epichlorohydrine	203-439-8	106-89-8	1.9	-	-	-	-	-	skin (10)	-
Ethylene dibromide	203-444-5	106-93-4	0.8	0.1	-	-	-	-	skin (10)	-
1,3-Butadiene	203-450-8	106-99-0	2.2	1	-	-	-	-	-	-
Ethylene dichloride	203-458-1	107-06-2	8.2	2	-	-	-	-	skin (10)	-
Hydrazine	206-114-9	302-01-2	0.013	0.01	-	-	-	-	skin (10)	-
Bromoethylene	209-800-6	593-60-2	4.4	1	-	-	-	-	-	-

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Diesel engine exhaust emissions	-	-	0.05(*)	-	-	-	-	-	-	The limit value shall apply from 21 February 2023. For underground mining and tunnel construction the limit value shall apply from 21 February 2026.
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of these regulations	-	-	-	-	-	-	-	-	skin (10)	-
Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine	-	-	-	-	-	-	-	-	skin (10)	-
Cadmium and its inorganic compounds	-	-	0.001 ⁽¹¹⁾	-	-	-	-	-	-	Limit value: 0.004 mg/m ³ ⁽¹²⁾ until 11 July 2027
Beryllium and inorganic beryllium compounds	-	-	0.0002 ⁽¹¹⁾	-	-	-	-	-	dermal and respiratory sensitisation ⁽¹³⁾	Limit value: 0.0006 mg/m ³ until 11 July 2026
Arsenic acid and its salts, as well as inorganic arsenic compounds	-	-	0.01 ⁽¹¹⁾	-	-	-	-	-	-	For the copper smelting sector, the limit value shall apply from 11 July 2023

Formaldehyde	200-001-8	50-00-0	0.37	0.3	-	0.74	0.6	-	dermal sensitisation ⁽¹⁴⁾	Limit value: 0.62 mg/m ³ or 0.5 ppm ⁽³⁾ for the health care, funeral and embalming sectors until 11 July 2024
4,4'-Methylenebis(2-chloroaniline)	202-918-9	101-14-4	0.01	-	-	-	-	-	skin ⁽¹⁰⁾	
Acrylonitrile	203-466-5	107-13-1	1	0.45	-	4	1.8	-	Skin ⁽¹⁰⁾ Dermal sensitisation ⁽¹⁴⁾	The limit values shall apply from 5 April 2026.
Nickel compounds	-	-	0.01 ⁽¹⁵⁾ 0.05 ⁽¹⁶⁾	-	-	-	-	-	Dermal and respiratory sensitisation ⁽¹³⁾	The limit value ⁽¹⁵⁾ shall apply from 18 January 2025. The limit value ⁽¹⁶⁾ shall apply from 18 January 2025. Until then a limit value of 0.1 mg/m ³ ⁽¹⁶⁾ shall apply.
Inorganic lead and its compounds	-	-	0.15	-	-	-	-	-	-	-
N,N-dimethylacetamide	204-826-4	127-19-5	36	10	-	72	20	-	Skin ⁽¹⁰⁾	-
Nitrobenzene	202-716-0	98-95-3	1	0.2	-	-	-	-	Skin ⁽¹⁰⁾	-

*PROTECTION OF WORKERS THE RISKS RELATED
TO EXPOSURE TO CARCINOGENS, MUTAGENS OR
REPROTOXIC SUBSTANCES AT WORK*

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N,N-Dimethyl- formamide	200- 679-5	68-12-2	15	5	-	30	10	-	Skin ⁽¹⁰⁾	-
2-Methoxyetha- nol	203- 713-7	109-86-4	-	1	-	-	-	-	Skin ⁽¹⁰⁾	-
2-Methoxyethyl acetate	203- 772-9	110-49-6	-	1	-	-	-	-	Skin ⁽¹⁰⁾	-
2-Ethoxyethanol	203- 804-1	110-80-5	8	2	-	-	-	-	Skin ⁽¹⁰⁾	-
2-Ethoxyethyl acetate	203- 839-2	111-15-9	11	2	-	-	-	-	Skin ⁽¹⁰⁾	-
1-Methyl-2- pyrrolidone	212- 828-1	872-50-4	40	10	-	80	20	-	Skin ⁽¹⁰⁾	-
Mercury and divalent inor- ganic mercury compounds including mer- cury oxide and mercury chlo- ride (measured as mercury)	-	-	0.02	-	-	-	-	-	-	-
Bisphenol A; 4,4'-Isopro- pylidenediphe- nol	201- 245-8	80-05-7	2 ⁽¹¹⁾	-	-	-	-	-	-	-
Carbon monox- ide	211- 128-3	630-08-0	23	20	-	117	100	-	-	-

- (1) EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, of Regulation (EC) No 1272/2008.
- (2) CAS No: Chemical Abstract Service Registry Number.
- (3) Measured or calculated in relation to a reference period of eight (8) hours time-weighted average (TWA)
- (4) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
- (5) mg/m³ = milligrams per cubic metre of air at 20 °C and 101.3 kPa (760 mm mercury pressure).
- (6) ppm = parts per million by volume in air (ml/m³).
- (7) f/ml = fibres per millilitre.
- (8) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.
- (9) Respirable fraction.
- (10) Substantial contribution to the total body burden via possible dermal exposure
- (11) Inhalable fraction
- (12) Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a monitoring system with a biological limit value not exceeding 0.002 mg Cd/g creatinine in urine.
- (13) The substance can cause sensitisation of the skin and of the respiratory tract.
- (14) The substance can cause sensitisation of the skin.
- (15) Respirable fraction, measured as nickel.
- (16) Inhalable fraction, measured as nickel.
- (*) Measured as elemental carbon.

Added by:
L.N. 102 of 2024.

SCHEDULE IV
BIOLOGICAL LIMIT VALUES AND HEALTH
SURVEILLANCE MEASURES
(Regulation 16(3))

1. Lead and its ionic compounds

Biological monitoring shall include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:

70 µg Pb/100 ml blood

Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0.075 mg/m³, calculated as a time-weighted average over forty (40) hours per week, or a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers."
