

EU Legal Definitions in Chemical Legislation

Term	Definition	Source
Active substance	A substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.	98/8/EC
Activity involving chemical agents	Any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work. [See Chemical agent]	98/24/EC
Actors in the supply chain	All manufacturers and/or importers and/or downstream users in a supply chain	Draft REACH regulation
Adverse effect	Serious damage (clear functional disturbance or morphological change which has toxicological significance). It is particularly important when these changes are irreversible. It is also important to consider not only specific severe changes in a single organ or biological system, but also generalised changes of a less severe nature involving several organs, or severe changes in general health status [see 67/548/EEC, 3.2.4 for further clarification]	Derived from 67/548/EEC
Aerosol dispenser	Any non-re-useable container made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state.	75/324/EEC
Alloy	A metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.	Draft REACH regulation
Alloy	A metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS.	GHS 2005
Article	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	Draft REACH regulation
Aspiration	The entry of a liquid or solid chemical product into the trachea and lower respiratory system directly through the oral or nasal cavity, or indirectly from vomiting.	GHS 2005
Aspiration hazard	Liquid substances and preparations which, because of their low viscosity, may cause lung damage if swallowed. Criteria for aspiration hazard: (a) Substances and preparations containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration of $\geq 10\%$; and having a low viscosity: (i) flow time of < 30 sec in a 3mm ISO cup (ISO 2431); (ii) a kinematic viscosity measured by a calibrated glass	Derived from 67/548/EEC

	<p>capillary viscometer (ISO 3104/3105) of $< 7 \times 10^{-6}$ m²/sec at 40 °C; (iii) a kinematic viscosity derived from measurements of rotational viscosity (ISO 3219) $< 7 \times 10^{-6}$ m²/sec at 40 °C.</p> <p>(b) Substances and preparations, based on practical experience in humans.</p> <p>(c) Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension > 33 mN/m at 25 °C (du Mouy tensiometer, or Annex V methods)</p>	
Authorisation	An administrative act by which the competent authority of a Member State authorises, following an application submitted by an applicant, the placing on the market of a biocidal product in its territory or in a part thereof.	98/8/EC
Basic substance	<p>A substance listed in Annex 1B, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which is not directly marketed for this biocidal use.</p> <p>The substances, which could potentially enter Annex 1B in accordance with the procedure laid down in Articles 10 and 11, are inter alia the following: carbon dioxide, nitrogen, ethanol, 2-propanol, acetic acid, kieselguhr.</p>	98/8/EC
Biocidal product	Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.	98/8/EC
Biological limit value	The limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or and indicator of effect.	98/24/EC
Carcinogen	<p>(a) A substance to which, in Annex 1 of 67/548/EEC, the risk-phrase R45 'may cause cancer' is applied.</p> <p>(b) A preparation which, under Article 3 (5) (j) of Directive 88/379/EEC, must be labelled as R45 'may cause cancer'.</p> <p>(c) A substance, a preparation or a process referred to in Annex 1 [of 90/394] as well as a substance or preparation released by a process referred to in Annex 1 [of 90/394],</p>	90/394/EEC
Carcinogen	A chemical substance or a mixture of chemical substances which induce cancer or increase its incidence.	GHS 2005
Carcinogenic	<p>Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.</p> <p>(a) Category 1: Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.</p> <p>(b) Category 2: Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of: (i) appropriate long-term animal studies; (ii) other relevant</p>	67/548/EEC

	<p>information.</p> <p>(c) Category 3: Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.</p> <p>Category 3 actually comprises 2 subcategories:</p> <p>(a) substances which are well investigated but for which the evidence of a tumour-inducing effect is insufficient for classification in category 2. Additional experiments would not be expected to yield further relevant information with respect to classification;</p> <p>(b) substances which are insufficiently investigated. The available data are inadequate, but they raise concern for man. This classification is provisional; further experiments are necessary before a final decision can be made.</p>	
Change in consistency	<p>The substance is used, for example, in the form of a paste or a granulate instead of in powder form.</p> <p>[See low-emission forms of use]</p>	67/548/EEC
Chemical agent	<p>Any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market.</p> <p>[See hazardous chemical agent]</p>	98/24/EC
Chemical identity	<p>A name that will uniquely identify a chemical. This can be a name that is in accordance with the nomenclature systems of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service.</p>	GHS 2005
Competent authority	<p>The authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation.</p>	Draft REACH regulation
Competent authority	<p>Any national body(ies) or authority(ies) designated or otherwise recognized as such in connection with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).</p>	GHS 2005
Compressed gas	<p>A gas which when packaged under pressure is entirely gaseous at $-50\text{ }^{\circ}\text{C}$; including all gases with a critical temperature $\leq -50\text{ }^{\circ}\text{C}$.</p>	GHS 2005
Contact sensitizer	<p>A substance that will induce an allergic response following skin contact. The definition for 'contact sensitizer' is equivalent to 'skin sensitizer'.</p> <p>[See Skin sensitizer]</p>	GHS 2005
Corrosive	<p>Substances and preparations, which may, on contact with living tissues, destroy them.</p> <p>A substance or preparation is considered to be corrosive if:</p> <p>(a) when it is applied to healthy intact animal skin, it produces full thickness destruction of skin tissue on at least once animal during the test for skin irritation (Annex V test or equivalent)</p> <p>(b) on the basis of results from a validated in vitro test (eg B40)</p>	67/548/EEC

	(c) if the result [of such testing] can be predicted, eg for strongly acidic or alkaline reaction indicated by pH ≤ 2 or ≥ 11.5 . For cases based on pH, acid/alkali reserve may be taken into consideration; if this indicates the substance or preparation may not be corrosive, then further testing (preferably validated in vitro test) should be carried out to confirm this. Consideration of acid/alkali reserve should not be used alone to exonerate substances or preparations from classification as corrosive.	
Corrosive to metals	A substance or mixture which by chemical action will materially damage, or even destroy, metals.	GHS 2005
Cosmetic product	Any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.	76/768/EEC
Critical temperature	The temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.	GHS 2005
Dangerous	Substances and preparations that have the following properties (see definitions of properties elsewhere in this list): <ul style="list-style-type: none"> (a) explosive (b) oxidising (c) extremely flammable (d) highly flammable (e) flammable (f) very toxic (g) toxic (h) harmful (i) corrosive (j) irritant (k) sensitising (l) carcinogenic (m) mutagenic (n) toxic for reproduction (o) dangerous for the environment 	67/548/EEC
Dangerous for the environment	Substances and preparations which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment. 1. Aquatic environment. Criteria for acute toxicity assessment: <ul style="list-style-type: none"> (a) Very toxic: LC_{50} (fish, 96 h) ≤ 1 mg/l; or EC_{50} (Daphnia, 48 h) ≤ 1 mg/l; or IC_{50} (algae, 48 h) ≤ 1 mg/l. (b) Toxic: $1 < LC_{50}$ (fish, 96 h) ≤ 10 mg/l; or $1 < EC_{50}$ (Daphnia, 48 h) ≤ 10 mg/l; or $1 < IC_{50}$ (algae, 48 h) ≤ 10 mg/l. (c) Harmful: $10 < LC_{50}$ (fish, 96 h) ≤ 100 mg/l; or $10 < EC_{50}$ (Daphnia, 48 h) ≤ 100 mg/l; or $10 < IC_{50}$ (algae, 48 h) ≤ 100 mg/l. 	67/548/EEC

	<p>Where it can be demonstrated in the case of highly coloured substances that algal growth is inhibited solely as a result of a reduction in light intensity, then the 72 h IC₅₀ for algae should not be used as a basis for classification.</p> <p>For long-term effects the following criteria are considered:</p> <ul style="list-style-type: none"> (a) ready degradability (b) $\log P_{ow} \geq 3$ (unless experimentally determined bioconcentration factor ≤ 100). <p>Also, substances not falling under the criteria listed above, but which on the basis of the available evidence concerning their toxicity may nevertheless present a danger to the structure and/or functioning of aquatic ecosystems.</p> <p>Also, substances not falling under the criteria listed above, but which, on the basis of the available evidence concerning their persistence, potential to accumulate, and predicted or observed environmental fate and behaviour may nevertheless present a long-term and/or delayed danger to the structure and/or functioning of aquatic ecosystems. For example, poorly water-soluble substances, i.e. substances with a solubility of less than 1 mg/l will be covered by this criterion if both: they are not readily degradable; and the $\log P_{ow} \geq 3.0$ (unless the experimentally determined BCF ≤ 100). This criterion applies to substances unless there exists additional scientific evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment. Such additional scientific evidence should normally be based on the studies required at level 1 (Annex VIII), or studies of equivalent value, and could include: either a proven potential to degrade rapidly in the aquatic environment; or an absence of chronic toxicity effects at the solubility limit (e.g. a no-observed effect concentration of greater than the solubility limit determined in a prolonged toxicity study with fish or daphnia).</p> <p>[See readily degradable]</p> <p>2. Terrestrial environment. Substances and preparations:</p> <ul style="list-style-type: none"> (a) Toxic to flora (b) Toxic to fauna (c) Toxic to soil organisms (d) Toxic to bees (e) May cause long-term adverse effects in the environment <p>Substances and preparations which on the basis of the available evidence concerning their toxicity, persistence, potential to accumulate and predicted or observed environmental fate and behaviour may present a danger, immediate or long-term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered [in the aquatic environment]. Detailed criteria will be elaborated later.</p> <p>3. Atmospheric environment. Substances which on the basis of the available evidence concerning their properties and their predicted or observed environmental fate and behaviour may present a danger to the structure and/or the functioning of the stratospheric ozone layer. This includes the substances which are listed in Annex I to Council Regulation (EC) No 2037/2000 (as amended) on substances that deplete the ozone layer.</p>	
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Dangerous substance	A substance, mixture or preparation listed in Annex 1, Part 1, or fulfilling the criteria laid down in Annex 1, Part 2 [of this Directive; comprising a list of hazardous substances, and R-phrase or transport hazard properties, respectively], and present as a raw material, product, by-product, residue or intermediate, including those substances which it is reasonable to suppose may be generated in the event of accident	96/82/EC (Seveso II)
Dermal corrosion	See Corrosive; also skin corrosion	
Dermal irritation	See Irritation; also Skin irritation	
Developmental toxicity	See Toxic for Reproduction	
Discriminating dose	The dose which causes evident toxicity but not mortality and must be one of the four dosage levels specified in Annex V (5, 50, 500 or 2000 mg/kg)	67/548/EEC
Dissolved gas	A gas which when packaged under pressure is dissolved in a liquid phase solvent.	GHS 2005
Distributor	Any natural or legal person established with the Community, including a retailer, who only stores and places on the market a substance, on its own or on a preparation, for third parties.	Draft REACH regulation
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or on a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(4)(c) shall be regarded as a downstream user.	Draft REACH regulation
Dust	Solid particles of a substance or mixture suspended in a gas (usually air)	GHS 2005
EC Number (or ECN)	A reference number used by the European Communities to identify dangerous substances, in particular those registered under EINECS.	GHS 2005
EC ₅₀	The effective concentration of substance that caused 50% of the maximum response	GHS 2005
Effective exhaust ventilation system	[See exhaust ventilation]	
EINECS	The European Inventory of Existing Commercial Chemical Substances. This inventory contains the definitive list of all chemical substances deemed to be on the Community market on 18 September 1981.	99/45/EC; and 67/548/EEC
EINECS	European Inventory of Existing Commercial Chemical Substances.	GHS 2005
Emission	Concerns the release of a substance from a system, for example when a system is breached. To guarantee a maximum level of protection for workers and the environment minimisation of emission through rigorous containment of the process must	67/548/EEC

	therefore be the primary aim. [See low-emission forms of use]	
Emission-free forms of use	For example, master batches without abrasion; ie the plastic matrix is so resistant to abrasion that no hazardous substance can be released. [See: low-emission forms of use]	67/548/EEC
Establishment	The whole area under the control of an operator where dangerous substances are present in one or more installations, including common or related infrastructures or activities	96/82/EC (Seveso II)
Evident toxicity	Toxic effects, after exposure to the substance tested, which are so severe that exposure to the next highest fixed dose [see discriminating dose] would probably lead to mortality	67/548/EEC
Exhaust ventilation system	<p>(a) Integrated exhaust ventilation system. An exhaust ventilation system of closed type, which is used in combination with locks, enclosures, housings, containers etc, in order to restrict the chemical agents to the inner part of the closed functional unit. Process-related openings must be as small as possible. The power of extraction and the air ducting must be designed so that there is sufficient underpressure within the extraction unit to ensure that all of the gases, vapours and/or dusts that occur are fully captured and carried away. Back-flow of the extracted hazardous substances into the working area must be prevented. This means that hazardous substances are prevented from escaping from the closed functional unit into the working area.</p> <p>(b) highly effective exhaust ventilation. An exhaust ventilation system of open and semi-open type which is dimensioned in such a way that chemical agents remain within the catchment area. This means that the occurrence of chemical agents in the workplace atmosphere can practically be excluded</p> <p>(c) effective exhaust ventilation system. An exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the chemical agents remain within the catchment area; i.e. the occurrence of chemical agents in the workplace atmosphere can be largely excluded or proof of adherence to the limit value is furnished.</p> <p>(d) other exhaust ventilation system. An exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the occurrence of chemical agents in the workplace atmosphere cannot be excluded.</p>	67/548/EEC
Existing substances	Substances listed in EINECS	793/93
Expendable packaging	The hazardous substance is enclosed in appropriate packaging and, without opening the packaging, is introduced into a reaction system together with this packaging. [See: low-emission forms of use]	67/548/EEC
Explosive	Solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen	67/548/EEC

	thereby quickly evolving gases, and which under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined	
Explosive article	An article containing one or more explosive substances. [See Explosive substance]	GHS 2005
Explosive atmosphere	A mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture.	1999/92/EC (ATEX 137)
Explosive substance	A solid or liquid substance (or mixture of substances) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic substances are included even when they do not evolve gases.	GHS 2005 ADR 2005
Exposure	Is concerned with what happens to a substance after it has been emitted, whether this is into the wider environment or whether the substance can be potentially inhaled or come in contact with the skin of a member of the workforce. If emissions can be anticipated to occur, rigorous exposure control must be achieved by appropriate techniques, noting the need to adopt the precautionary principle in that physico-chemical, toxicological and ecotoxicological properties which had not been tested shall be assumed as being hazardous.	67/548/EEC
Exposure scenario	The set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.	Draft REACH regulation
Extremely flammable	Liquid substances and preparations having an extremely low flash-point and low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure Criteria for liquids: fp < 0 °C; bp ≤ 35 °C	67/548/EEC
Eye irritant	Substances and preparations that, when applied to the eye of the animal, cause significant ocular lesions which occur within 72 h after exposure and which persist for at least 24 h. Ocular lesions are significant if the mean scores of the eye irritation test (Annex V method) have any of the following values: <ul style="list-style-type: none"> (a) $2 \leq \text{cornea opacity} < 3$ (b) $1 \leq \text{iris lesion} \leq 1.5$ (c) redness of the conjunctivae ≥ 2.5 (d) oedema of the conjunctivae (chemosis) ≥ 2 Or, in the case where the Annex V test has been completed using three animals, if the lesions on two or more animals are equivalent to any of the above values, except that for iris lesion the value should be ≥ 1 but < 2 , and for the redness of the conjunctivae the value should be ≥ 2.5 . In both cases, all scores at each of the reading times (24, 48, and 72 h) for an effect should be used in calculating the respective mean values.	

	<p>Also, substances and preparations that cause significant ocular lesions, based on practical observations in humans.</p> <p>Also, organic peroxides, except where evidence to the contrary is available.</p> <p>[See also severe eye irritant]</p>	
Eye irritation	<p>The production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.</p> <p>[See Irritant]</p>	GHS 2005
Flammable	<p>Liquid substances and preparations having a low flash point</p> <p>Criteria: $21 \leq fp \leq 55$ °C; such a preparation need not be classified if it could not support combustion and there is no reason to fear risks t those handling these preparations or to other persons.</p>	67/548/EEC
Flammable gas	<p>A gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa.</p>	GHS 2005
Flammable liquid	<p>A liquid having a flash point of not more than 93 °C.</p>	GHS 2005
Flammable solid	<p>A solid which is readily combustible, or may cause or contribute to fire through friction.</p>	GHS 2005
Flash point	<p>The lowest temperature (corrected to a standard pressure of 101.3 kPa) at which the application of an ignition source causes the vapours of a liquid to ignite under specified test conditions.</p>	GHS 2005
Frame-formulation	<p>Specifications for a group of biocidal products having the same use and user type.</p> <p>This group of products must contain the same active substances of the same specifications, and their compositions must present only variations from a previously authorised biocidal product which do not affect the level of risk associated with them and their efficacy.</p> <p>In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy.</p>	98/8/EC
Full study report	<p>A complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed.</p>	Draft REACH regulation
Gas	<p>A substance which:</p> <ul style="list-style-type: none"> (a) at 50 °C has a vapour pressure > 300 kPa (b) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa. 	GHS 2005
GHS	<p>The Globally Harmonized System of Classification and Labelling of Chemicals.</p>	GHS 2005
Good laboratory practice (GLP)	<p>GLP is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored,</p>	2004/10/EC

	recorded, archived and reported.	
Harmful	<p>Substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed, or absorbed via the skin.</p> <p>Criteria for acute oral toxicity:</p> <ul style="list-style-type: none"> (a) $200 < LD_{50} \text{ (rat)} \leq 2000 \text{ mg/kg}$ (b) Discriminating dose 50 mg/kg (rat): 100% survival but evident toxicity (c) Less than 100% survival at 500 mg/kg by the fixed dose procedure (d) High mortality in the dose range >200 to $\leq 200 \text{ mg/kg}$ (rat) by the acute toxic class method <p>Criteria for acute dermal toxicity:</p> <ul style="list-style-type: none"> (a) $400 < LD_{50} \text{ (rat, rabbit)} \leq 2000 \text{ mg/kg}$ <p>Criteria for acute inhalation toxicity:</p> <ul style="list-style-type: none"> (a) $1 < LC_{50} \text{ (rat)} \leq 5 \text{ mg/litre/4 h}$ (aerosols or particulates) (a) $2 < LC_{50} \text{ (rat)} \leq 20 \text{ mg/litre/4 h}$ (gases and vapours) <p>Criteria for repeated-dose oral toxicity:</p> <ul style="list-style-type: none"> (a) NOAEL (rat; 90 d study) $\leq 50 \text{ mg/kg/day}$ (b) NOAEL (rat; 28 d study) $\leq 150 \text{ mg/kg/day}$ (c) NOAEL (rat; 2 year study), case-by-case <p>Criteria for repeated-dose dermal toxicity:</p> <ul style="list-style-type: none"> (a) NOAEL (rat or rabbit; 90 d study) $\leq 100 \text{ mg/kg/day}$ (b) NOAEL (rat or rabbit; 28 d study) $\leq 300 \text{ mg/kg/day}$ (c) NOAEL (rat or rabbit; 2 year study), case-by-case <p>Criteria for repeated-dose inhalation toxicity:</p> <ul style="list-style-type: none"> (a) NOAEL (rat; 90 d study) $\leq 0.25 \text{ mg/l/6 h day}$ (b) NOAEL (rat; 28 d study) $\leq 0.75 \text{ mg/kg/day}$ (c) NOAEL (rat; 2 year study), case-by-case. <p>Note for multiple results, those from longest duration study should normally be used. See NOAEL, and adverse effect for further explanation.</p> <p>[See also very toxic, and harmful]</p> <p>[See also aspiration hazard – these substances also classified as harmful]</p>	67/548/EEC
Harmful organism	Any organism that has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.	98/8/EC
Hazard	The intrinsic property of a chemical agent with the potential to cause harm [See Chemical agent]	98/24/EC
Hazard	The intrinsic property of a dangerous substance or physical situation, with a potential for creating damage to human health and/or the environment	96/82/EC (Seveso II)
Hazard category	The division of criteria within each hazard class, eg oral acute	GHS 2005

	toxicity includes five hazard categories and flammable liquids includes four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.	
Hazard class	The nature of the physical, health, or environmental hazard, eg flammable solid, carcinogen, oral acute toxicity.	GHS 2005
Hazard statement	A statement assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including where appropriate, the degree of hazard.	GHS 2005
Hazardous chemical agent	<p>(a) Any chemical agent that meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive 67/548/EEC, whether or not that substance is classified under that Directive, other than those substances which only meet the criteria for classification as dangerous for the environment</p> <p>(b) Any chemical agent that meets the criteria for classification as a dangerous preparation according to the criteria in Annex VI to Directive 88/39/EEC, whether or not that preparation is classified under that Directive, other than those preparations which only meet the criteria for classification as dangerous for the environment</p> <p>(c) Any chemical agent which, whilst not meeting the criteria for classification as dangerous in accordance with (a) or (b), may, because of its physico-chemical chemical or toxicological properties and the way it is used or is present in the workplace present a risk to the safety and health of workers, including any chemical agent assigned an occupational exposure limit value.</p> <p>[See Chemical agent] [See Dangerous] [See Dangerous for the environment]</p>	98/24/EC
Health surveillance	The assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific chemical agents at work [See Chemical agent]	98/24/EC
Highly effective exhaust ventilation	[See exhaust ventilation]	
Highly flammable	<p>(a) Substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy</p> <p>(b) Solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition</p> <p>(c) Liquid substances and preparations having a very low flash point</p> <p>(d) Substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities, at a minimum rate of 1 litre per kilogram per hour</p>	67/548/EEC

	Criteria for liquids: fp < 21 °C, but not extremely flammable	
Identified use	A use of a substance on its own or in a preparation, or a use of a preparation that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.	Draft REACH regulation
Import	Physical introduction into the customs territory of the Community	Draft REACH regulation
Importer	Any natural or legal person established within the Community who is responsible for import	Draft REACH regulation
Importing	Bringing into the customs territory of the community	793/93
Initial boiling point	The temperature of a liquid at which its vapour pressure is equal to the standard pressure (101.3 kPa), ie the first gas bubble appears.	GHS 2005
Installation	A technical unit within an establishment in which dangerous substances are produced, used, handled or stored. It shall include all the equipment, structures, pipework, machinery, tools, private railway sidings, docks, unloading quays serving the installation, jetties, warehouses or similar structures, floating or otherwise, necessary for the operation of the installation.	96/82/EC (Seveso II)
Integrated exhaust ventilation system	[See exhaust ventilation]	67/548/EEC
Intermediate	A chemical substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another chemical substance(s)	67/548/EEC
Intermediate	<p>A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called synthesis):</p> <ul style="list-style-type: none"> (a) non-isolated intermediate: an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture; (b) on-site isolated intermediate: an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities; (c) transported isolated intermediate: an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites. 	Draft REACH regulation
Irritant	<p>Non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation.</p> <p>[See also skin irritant]</p>	67/548/EEC

	[See also eye irritant]	
IUPAC	The International Union of Pure and Applied Chemistry	GHS 2005
Label	An appropriate group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector(s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product.	GHS 2005
Label element	One type of information that has been harmonized for use in a label, eg pictogram, signal word	GHS 2005
LC ₅₀	The concentration of a chemical in air or of a chemical in water which causes the death of 50% (one half) of a group of test animals.	GHS 2005
LD ₅₀	The amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals	GHS 2005
Letter of access	A document, signed by the owner or owners of relevant data protected under the provisions of this Directive, which states that these data may be used by the competent authority for the purpose of granting an authorisation or a registration of a biocidal product under this Directive.	98/8/EC
Liquefied gas	A gas which when packaged under pressure is partially liquid at temperatures above -50 °C. A distinction is made between: <ul style="list-style-type: none"> (a) High pressure liquefied gas; a gas with a critical temperature between -50 and +65 °C (b) Low pressure liquefied gas: a gas with a critical temperature above +65 °C. 	GHS 2005
Liquid	A substance or mixture which at 50 °C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to the ASTM D 4359-90 test; or to the test for determining fluidity (penetrometer test) prescribed in Section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).	GHS 2005
Low-emission forms of use	Examples are: <ul style="list-style-type: none"> (a) expendable packaging; ie the hazardous substance is enclosed in appropriate packaging and, without opening the packaging, is introduced into a reaction system together with this packaging (b) change in consistency; ie the substance is used, for example, in the form of a paste or a granulate instead of in powder form, (c) master batch; this means that the hazardous substance is surrounded by a plastic matrix which prevents direct contact with the hazardous substance. The plastic matrix itself is not a hazardous substance. Abrasion of the plastic matrix and therefore of the hazardous substance, is, however, possible [see emission-free forms of use] 	67/548/EEC
Low-risk	A biocidal product which contains as active substance(s) only one	98/8/EC

biocidal product	<p>or more of those listed in Annex 1A and which does not contain any substance(s) of concern.</p> <p>Under the conditions of use, the biocidal product shall pose only a low risk to humans, animals and the environment.</p>	
Major accident	An occurrence such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by this Directive, and leading to serious danger to human health and/or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances.	96/82/EC (Seveso II)
Manufacturer	Any natural or legal person established within the Community who manufactures a substance within the community.	Draft REACH regulation
Manufacturing	Production or extraction of substances in the natural state	Draft REACH regulation
Master batch	<p>This means that the hazardous substance is surrounded by a plastic matrix that prevents direct contact with the hazardous substance. The plastic matrix itself is not a hazardous substance. Abrasion of the plastic matrix and therefore of the hazardous substance, is, however, possible.</p> <p>[See: low-emission forms of use]</p>	67/548/EEC
Mist	Liquid droplets of a substance or mixture suspended in a gas (usually air)	GHS 2005
Mixture	A mixture or solution composed of two or more substances in which they do not react.	GHS 2005
Monomer	A substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.	Draft REACH regulation
Mutagen	<p>An agent that gives rise to an enhanced occurrence of mutations.</p> <p>[See Mutation]</p>	67/548/EEC
Mutagen	An agent giving rise to an increased occurrence of mutations in populations of cells and/or organisms	GHS 2005
Mutagenic	<p>Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence.</p> <p>(a) Category 1: Substances known to be mutagenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage. To place a substance in category 1, positive evidence from human mutation epidemiology studies will be needed. Examples of such substances are not known to date. It is recognised that it is extremely difficult to obtain reliable information from studies on the incidence of mutations in human populations, or on possible increases in their frequencies.</p> <p>(b) Category 2: Substances which should be regarded as if they are mutagenic to man. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of</p>	67/548/EEC

	<p>heritable genetic damage, generally on the basis of: (i) appropriate animal studies; (ii) other relevant information. To place a substance in category 2, positive results are needed from assays showing: (i) mutagenic effects; or (ii) other cellular interactions relevant to mutagenicity, in germ cells of mammals in vivo; or (iii) mutagenic effects in somatic cells of mammals in vivo in combination with clear evidence that the substance or a relevant metabolite reaches the germ cells.</p> <p>(c) Category 3: Substances which cause concern for man owing to possible mutagenic effects. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in category 2. To place a substance in category 3, positive results are needed in assays showing (i) mutagenic effects; or (ii) other cellular interaction relevant to mutagenicity, in somatic cells in mammals in vivo. The latter especially would normally be supported by positive results from in vitro mutagenicity assays.</p> <p>It should be noted that substances are classified as mutagens with specific reference to inherited genetic damage. However, the type of results leading to classification of chemicals in category 3: 'induction of genetically relevant events in somatic cells' is generally also regarded as an alert for possible carcinogenic activity.</p> <p>Method development for mutagenicity testing is an ongoing process. For many new tests no standardised protocols and evaluation criteria are presently available. For the evaluation of mutagenicity data the quality of the test performance and the degree of validation of the test method have to be considered.</p>	
Mutation	A mutation is a permanent change in the amount or structure of the genetic material in an organism, resulting in a change of the phenotypic characteristics of the organism. The alterations may involve a single gene, a block of genes, or a whole chromosome. Effects involving single genes may be a consequence of effects on single DNA bases (point mutations) or of large changes, including deletions, within the gene. Effects on whole chromosomes may involve structural or numerical changes. A mutation in the germ cells in sexually reproducing organisms may be transmitted to the offspring.	67/548/EEC
Mutation	A permanent change in the amount or structure of the genetic material in a cell.	GHS 2005
NOAEL (no observed adverse effect level)	Highest dose at which no adverse effect (see elsewhere in list) is observed	Derived from 67/548/EEC
NOEC	No observed effect concentration	GHS 2005
Not chemically modified substance	A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities.	Draft REACH regulation
Notification	The documents, with the requisite information, presented to the competent authority of a Member State:	67/548/EEC

	<p>(a) For substances manufactured within the Community, by the manufacturer who places a substance wither on its own or in a preparation on the market</p> <p>(b) For substances manufactured outside the Community, by any person established in the Community who is responsible for placing the substance either on its own or in a preparation on the Community market, or alternatively by the person established within the Community who is, for the purposes of submitting a notification for a given substance placed on the Community market, either on its own or in a preparation, designated by the manufacturer as his sole representative.</p> <p>The person submitting the notification, as described above, shall be referred to as the notifier.</p>	
Notified substance	A substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC.	Draft REACH regulation
Notifier	See notification, above	
Occupational exposure limit value	Unless otherwise specified, the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period.	98/24/EC
Operator	Any individual or corporate body who operates or holds an establishment or installation or, if provided for by national legislation, has been given decisive economic power in the technical operation thereof	96/82/EC (Seveso II)
Organic peroxide	A liquid or solid organic substance which contains the bivalent -O-O- structure and may be considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures).	GHS 2005
Other exhaust ventilation system	[See exhaust ventilation]	
Oxidising	Substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances	67/548/EEC
Oxidising gas	Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.	GHS 2005
Oxidising liquid	A liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.	GHS 2005
Oxidising solid	A solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.	GHS 2005
Participant	A producer, formulator or association which has submitted a notification that has been accepted by the Commission inn accordance with Article 4 (2) of Regulation 1896/2000 [First Review Regulation] or a Member State which has indicated and interest in accordance with Article 5 (3) of that Regulation.	98/8/EC

Per year	Per calendar year unless stated otherwise	Draft REACH regulation
Phase-in substance	<p>A substance which meets at least one of the following criteria:</p> <ul style="list-style-type: none"> (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS); (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this; (c) it was placed on the market in the Community, or in the countries acceding to the EU on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this. 	Draft REACH regulation
Pictogram	A graphical composition that may include a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information.	GHS 2005
Placing on the market	Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.	Draft REACH regulation
Placing on the market	Making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market.	99/45/EC; and 67/548/EEC
Placing on the market	Any supply, whether in return for payment or free of charge, or subsequent storage other than storage followed by consignment from the customs territory of the Community or disposal. Importation of a biocidal product into the customs territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive.	98/8/EC
Polymer	<p>A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:</p> <ul style="list-style-type: none"> (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight <p>In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer.</p>	Draft REACH regulation
Polymer	A substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight	99/45/EC; and 67/548/EEC

	majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a 'monomer unit' means the reacted form of a monomer in a polymer.	
Precautionary statement	A phrase (and/or pictogram) that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product.	GHS 2005
Preparation	A mixture or solution composed of two or more substances	Draft REACH regulation; and 99/45/EC; and 67/548/EEC
Process orientated research and development	The further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance. See also: Product and process orientated research and development	99/45/EEC; and 67/548/EEC
Producing	The production of substances which are isolated in a solid, liquid, or gaseous form	793/93
Product and process orientated research and development	Any scientific development related to product development, the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance.	Draft REACH regulation
Product identifier	The name or number used for a hazardous product on a label or in the SDS. It provides a unique means by which the product user can identify the substance or mixture within the particular use setting, eg transport, consumer or workplace.	GHS 2005
Pyrophoric liquid	A liquid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air.	GHS 2005
Pyrophoric solid	A solid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air.	GHS 2005
Pyrotechnic article	An article containing one or more pyrotechnic substances	GHS 2005
Pyrotechnic substance	A substance or mixture of substances designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative, self-sustaining exothermic chemical reactions.	GHS 2005 ADR 2005
QSAR	Quantitative structure–activity relationship	GHS 2005
Readily combustible solid	Powdered, granular, or pasty substance or mixture which is dangerous if it can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.	GHS 2005
Readily degradable	Substances are considered readily degradable if the following criteria hold true: (a) if in 28-day biodegradation studies the following levels	67/548/EEC

	<p>of degradation are achieved: (i) in tests based upon dissolved organic carbon: 70%; (ii) in tests based upon oxygen depletion or carbon dioxide generation: 60% of the theoretical maxima. These levels of biodegradation must be achieved within 10 days of the start of degradation, which point is taken as the time when 10% of the substance has been degraded.</p> <p>(b) if in those cases where only COD and BOD₅ data are available when the ratio of BOD₅/COD is greater than or equal to 0.5.</p> <p>(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of > 70% within a 28-day period.</p>	
Recipient of a substance or preparation	A downstream user or a distributor being supplied with a substance or preparation	Draft REACH regulation
Recipient of an article	An industrial or professional user being supplied with an article, but does not include consumers	Draft REACH regulation
Refrigerated liquefied gas	A gas which when packaged is made partially liquid because of its low temperature.	GHS 2005
Registrant	The manufacturer or the importer or the producer or importer of an article submitting a registration for a substance.	Draft REACH regulation
Registrant's own use	An industrial or professional use by the registrant	Draft REACH regulation
Registration	An administrative act by which the competent authority of a Member State, following an application submitted by an applicant, after verification that the dossier meets the relevant requirements of this Directive, allows the placing on the market of a low-risk biocidal product in its territory or in a part thereof.	98/8/EC
Reproductive toxicant	See toxic for reproduction	
Residues	One or more of the substances present in a biocidal product which remains as a result of its use including the metabolites of such substances and products resulting from their degradation or reaction.	98/8/EC
Respiratory irritant	<p>Substances and preparations which cause serious irritation to the respiratory system based on:</p> <p>(a) practical observations in humans</p> <p>(b) positive results from appropriate animal tests</p> <p>In interpreting practical observations in humans, care should be taken to distinguish between effects that lead to classification with R48 [repeated-dose toxicity effects] from those leading to classification with R37 [respiratory irritation]; the latter effects are reversible and usually limited to the upper airways.</p> <p>Positive results from appropriate animal tests may include data obtained in a general toxicity test, including histopathological data from the respiratory system. Data from the measurement of experimental bradypnea may also be used to assess airway</p>	67/548/EEC

	irritation.	
Respiratory sensitiser	<p>Substances and preparations, based on the following criteria:</p> <ul style="list-style-type: none"> (a) induction of specific respiratory hypersensitivity (b) where there are positive results from appropriate animal tests, or (c) if the substance is an isocyanate, unless there is evidence that the specific isocyanate does not cause respiratory hypersensitivity. <p>Evidence that the substance or preparation can induce specific respiratory hypersensitivity will normally be based on human experience. In this context hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.</p> <p>When considering the evidence from human exposure, it is necessary for a decision on classification to take into account in addition to the evidence from the cases:</p> <ul style="list-style-type: none"> (a) the size of the population exposed (b) the extent of exposure. <p>The evidence referred to above could be:</p> <ul style="list-style-type: none"> (a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include: <ul style="list-style-type: none"> (i) a chemical structure related to substances known to cause respiratory hypersensitivity, (ii) an in vivo immunological test (e.g. skin prick test), (iii) an in vitro immunological test (e.g. serological analysis), (iv) studies indicating other specific but non-immunological mechanisms of action, e.g. repeated low-level irritation, pharmacologically mediated effects, or (v) data from a positive bronchial challenge test with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction. <p>Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance or preparation and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood, and smoking history.</p> <p>The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is however recognised that in practice many of the examinations listed above will already have been carried out.</p> <p>Substances that elicit symptoms of asthma by irritation only in people with bronchial hyperreactivity should not be assigned R42.</p> <p>Animal studies. Data from tests which may be indicative of the</p>	67/548/EEC

	<p>potential of a substance or preparation to cause sensitisation by inhalation in humans may include:</p> <p>(a) IgE measurements (e.g. in mice), or</p> <p>(b) specific pulmonary responses in guinea pigs.</p> <p>[See also skin sensitisation]</p>	
Respiratory sensitizer	A substance that induces hypersensitivity of the airways following inhalation of the substance.	GHS 2005
Restriction	Any condition for or prohibition of the manufacture, use or placing on the market	Draft REACH regulation
Risk	The likelihood that the potential for harm will be attained under the conditions of use and/or exposure	98/24/EC
Risk	The likelihood of a specific effect occurring within a specified period or in specified circumstances	96/82/EC (Seveso II)
Robust study summary	A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report.	Draft REACH regulation
SAR	Structure–activity relationship	GHS 2005
Scientific research and development	Any scientific experimentation, analysis, or chemical research carried out under controlled conditions in a volume less than 1 tonne per year.	Draft REACH regulation
Scientific research and development	Any scientific experimentation, analysis, or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development.	99/45/EC; and 67/548/EEC
SDS	Safety data sheet	GHS 2005
Self-accelerating decomposition temperature (SADT)	The lowest temperature at which self-accelerating decomposition may occur with substance as packaged.	GHS 2005
Self-heating substance	A solid or liquid substance, other than a pyrophoric substance, which by reaction with air and without energy supply, is liable to self-heat; this substance differs from a pyrophoric substance in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).	GHS 2005
Self-reacting substance	A thermally unstable liquid or solid substance liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances or mixtures classified under the GHS as explosive, organic peroxides or as oxidising.	GHS 2005
Sensitizing	<p>Substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced.</p> <p>[See respiratory sensitiser]</p> <p>[See skin sensitiser]</p>	67/548/EEC

Serious damage	eye	The production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.	GHS 2005
Severe irritant	eye	<p>Substances and preparations which, when applied to the eye of the animal, cause severe ocular lesions which occur within 72 h of exposure and which persist for at least 24 h.</p> <p>Ocular lesions are severe if the means of the scores of the eye irritation test in Annex V have any of the values.</p> <p>(a) cornea opacity > 3 (b) iris lesion > 1.5</p> <p>The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values:</p> <p>(a) cornea opacity > 3 (b) iris lesion = 2</p> <p>In both cases, all scores at each of the reading times (24, 48, and 72 h) for an effect should be used in calculating the respective mean values.</p> <p>Ocular lesions are also severe when they are still present at the end of the observation time.</p> <p>Ocular lesions are also severe if the substance or preparation causes irreversible discoloration of the eyes.</p> <p>Also, substances and preparations which cause severe ocular lesions, based on practical experience in humans.</p> <p>Note: when a substance or preparation is classified as corrosive and assigned R34 or R35, the risk of severe damage to eyes is considered implicit, and R41 is not included on the label.</p> <p>[See also eye irritant]</p>	67/548/EEC
Signal word		A word that indicates the relative level of severity of hazards to alert the reader to a potential hazard on the label. The following two levels are distinguished: (a) <i>Danger</i> : a signal word indicating the more severe hazard categories; (b) <i>Warning</i> : a signal word indicating the less severe hazard categories	GHS 2005
Site		A single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared.	Draft REACH regulation
Skin corrosion		The production of irreversible damage to the skin following the application of a test substance for up to 4 h. [See Corrosion]	GHS 2005
Skin irritant		<p>A substance or preparation is considered to be irritant if they cause significant inflammation of the skin which persists for at least 24 h after an exposure period of up to four hours determined on the rabbit according to the cutaneous irritation test (Annex V test).</p> <p>Inflammation of the skin is significant if:</p> <p>(a) the mean value of the scores for either erythema and eschar formation or oedema formation calculated over all the animals tested is 2 or more</p> <p>(b) in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of two</p>	67/548/EEC

	<p>or more calculated for each animal separately has been observed in two or more animals.</p> <p>In both cases, all scores at each of the 24, 48 and 72 h reading times for an effect should be used in calculating respective mean values.</p> <p>Inflammation is also significant if it persists in at least two animals at the end of the observation time. Particular effects, eg hyperplasia, scaling, discoloration, fissures, scabs and alopecia should be taken into account.</p> <p>Relevant data may also be considered from non-acute animal studies. These are considered significant if the effects seen are comparable to those described above.</p> <p>Also, substances and preparations that cause significant inflammation of the skin based on practical observations in humans on immediate, prolonged or repeated contact.</p> <p>Also, organic peroxides, except where evidence to the contrary is available.</p>	
Skin irritation	<p>The production of reversible damage to the skin following the application of a test substance for up to 4 h.</p> <p>[See skin irritant]</p>	GHS 2005
Skin sensitiser	<p>Substances and preparations, based on the following criteria:</p> <ul style="list-style-type: none"> (a) if practical experience shows the substance or preparation to be capable of inducing a sensitisation by skin contact in a substantial number of persons, or (b) where there are positive results from an appropriate animal test. <p>Human evidence. The following evidence (practical experience) is sufficient to classify a substance or preparation with R43:</p> <ul style="list-style-type: none"> (a) positive data from appropriate patch testing, normally in more than one dermatological clinic, or (b) epidemiological studies showing allergic contact dermatitis caused by the substance or preparation. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small, or (c) positive data from experimental studies in man (see also 3.1.1). <p>The following is sufficient to classify a substance with R43 when there is supportive evidence:</p> <ul style="list-style-type: none"> (a) isolated episodes of allergic contact dermatitis, or (b) epidemiological studies where chance, bias or confounders have not been ruled out fully with reasonable confidence. <p>Supportive evidence may include:</p> <ul style="list-style-type: none"> (a) data from animal tests performed according to existing guidelines, with a result that does not meet the criteria given in the section on animal studies but is sufficiently close to the limit to be considered significant, or (b) data from non-standard methods, or (c) appropriate structure-activity relationships. 	

	<p>Animal studies. Positive results from appropriate animal tests are:</p> <p>(a) in the case of the adjuvant type test method for skin sensitisation detailed in Annex V or in the case of other adjuvant-type test methods, a response of at least 30% of the animals is considered positive,</p> <p>(b) for any other test method a response of at least 15 % of the animals is considered positive.</p> <p>[See also respiratory sensitiser]</p>	
Skin sensitizer	A substance that will induce an allergic response following skin contact. The definition for 'skin sensitizer' is equivalent to 'contact sensitizer'.	GHS 2005
Small and medium enterprises (SME)	Small and medium enterprises according to the definition contained in Commission Recommendation concerning the definition of micro, small and medium-sized enterprises (OJ L124 20.5.2003, p 36)	Draft REACH regulation
Solid	A substance or mixture which does not meet the definition of liquid or gas.	GHS 2005
SPR	Structure property relationship	GHS 2005
Storage	The presence of a quantity of dangerous substances for the purposes of warehousing, depositing in safe custody or keeping in stock	96/82/EC (Seveso II)
Study summary	A summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study for hazard assessment	Draft REACH regulation
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.	Draft REACH regulation; and 99/45/EC; and 67/548/EEC
Substance	Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.	GHS 2005
Substance of concern	<p>Any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to create such an effect.</p> <p>Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to Council Directive 67/548/EEC [Dangerous Substances Directive], and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Council Directive 88/379/EEC [Dangerous Preparations Directive].</p>	98/8/EC
Substance which, in contact with	A solid or liquid substance or mixture which, by interaction with water, is liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.	GHS 2005

water, emits flammable gases		
Substances which occur in nature	A naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means; by dissolution in water, by flotation, by extraction with water, by steam distillation, or by heating solely to remove water or which is extracted from air by any means.	Draft REACH regulation
Supplemental label element	Any additional non-harmonized type of information supplied on the container of a hazardous product that is not required or specified under the GHS. In some cases this information may be required by other competent authorities or it may be additional information provided at the discretion of the manufacturer/distributor.	GHS 2005
Supplier of a substance or preparation	Any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation	Draft REACH regulation
Symbol	A graphical element intended to succinctly convey information.	GHS 2005
Technical name	A name that is generally used in commerce, regulations and codes to identify a substance or mixture, other than the IUPAC or CAS name, and that is recognized by the scientific community. Examples of technical names include those used for complex mixtures (eg, petroleum fractions or natural products), pesticides (eg, ISO or ANSI systems), dyestuffs (Colour Index system) and minerals.	GHS 2005
Technically leakproof	Applied to a subunit if a leak is not discernible during testing, monitoring or checking for leakproofness, e.g. using foaming agents or leak searching/indicating equipment performed for the particular use. Systems, subsystems and functional elements are technically leakproof, if the rate of leakage is $< 0.00001 \text{ mbar} \cdot \text{l}^*/\text{s}$.	67/548/EEC
Toxic	<p>Substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.</p> <p>Criteria for acute oral toxicity:</p> <ul style="list-style-type: none"> (a) $25 < \text{LD}_{50} \text{ (rat)} \leq 200 \text{ mg/kg}$ (b) Discriminating dose 5 mg/kg (rat): 100% survival but evident toxicity (c) High mortality at doses > 25 to $\leq 200 \text{ mg/kg}$ (rat) by the acute toxic class method <p>Criteria for acute dermal toxicity:</p> <ul style="list-style-type: none"> (b) $50 < \text{LD}_{50} \text{ (rat, rabbit)} \leq 400 \text{ mg/kg}$ <p>Criteria for acute inhalation toxicity:</p> <ul style="list-style-type: none"> (a) $0.25 < \text{LC}_{50} \text{ (rat)} \leq 1 \text{ mg/litre/4 h}$ (aerosols or particulates) (c) $0.5 < \text{LC}_{50} \text{ (rat)} \leq 2 \text{ mg/litre/4 h}$ (gases and vapours) <p>Or strong evidence that irreversible damage other than [specific CMR effects] is likely to be caused by a single exposure by an appropriate route, generally in the above-mentioned dose range.</p> <p>Criteria for repeated-dose oral toxicity:</p> <ul style="list-style-type: none"> (a) $\text{NOAEL (rat; 90 d study)} \leq 5 \text{ mg/kg/day}$ 	67/548/EEC

	<p>(b) NOAEL (rat; 28 d study) \leq 15 mg/kg/day (c) NOAEL (rat; 2 year study), case-by-case</p> <p>Criteria for repeated-dose dermal toxicity:</p> <p>(a) NOAEL (rat or rabbit; 90 d study) \leq 10 mg/kg/day (b) NOAEL (rat or rabbit; 28 d study) \leq 30 mg/kg/day (c) NOAEL (rat or rabbit; 2 year study), case-by-case</p> <p>Criteria for repeated-dose inhalation toxicity:</p> <p>(a) NOAEL (rat; 90 d study) \leq 0.025 mg/l/6 h day (b) NOAEL (rat; 28 d study) \leq 0.075 mg/kg/day (c) NOAEL (rat; 2 year study), case-by-case</p> <p>Note for multiple results, those from longest duration study should normally be used. See NOAEL, and adverse effect for further explanation.</p> <p>[See also very toxic, and harmful]</p>	
<p>Toxic for reproduction</p>	<p>Substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity.</p> <p>Reproductive toxicity includes impairment of male and female reproductive functions or capacity and the induction of non-inheritable harmful effects on the progeny. This may be classified under two main headings:</p> <ol style="list-style-type: none"> 1. Effects on male or female fertility, including adverse effects on libido, sexual behaviour, any aspect of spermatogenesis or oogenesis, or on hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or the development of the fertilised ovum up to and including implantation; 2. Developmental toxicity, taken in its widest sense to include any effect interfering with normal development, both before and after birth. It includes effects induced or manifested prenatally as well as those manifested postnatally. This includes embryotoxic–fetotoxic effects such as reduced body weight, growth and developmental retardation, organ toxicity, death, abortion, structural defects (teratogenic effects), functional defects, peri-postnatal defects, and impaired postnatal mental or physical development up to and including normal pubertal development. <p>Classification of chemicals as toxic to reproduction is intended to be used for chemicals which have an intrinsic or specific property to produce such toxic effects. Chemicals should not be classified as toxic to reproduction where such effects are solely produced as a non-specific secondary consequence of other toxic effects. Chemicals of most concern are those which are toxic to reproduction at exposure levels which do not produce other signs of toxicity.</p> <p>(a) Category 1: (i) Substances known to impair fertility in humans. There is sufficient evidence to establish a causal relationship between human exposure to the substance and impaired fertility; (ii) substances known to cause developmental toxicity in humans. There is sufficient evidence to establish a causal relationship between human exposure to the substance and subsequent</p>	<p>67/548/EEC</p>

	<p>developmental toxic effects in the progeny.</p> <p>(b) Category 2: (i) Substances which should be regarded as if they impair fertility in humans. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of either: clear evidence in animal studies of impaired fertility in the absence of toxic effects, or, evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary non-specific consequence of the other toxic effects; or other relevant information. (ii) Substances which should be regarded as if they cause developmental toxicity to humans. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in developmental toxicity, generally on the basis of either: clear results in appropriate animal studies where effects have been observed in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects; or other relevant information.</p> <p>(c) Category 3: (i) Substances which cause concern for human fertility, generally on the basis of either: results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which is not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in category 2; or other relevant information. (ii) Substances which cause concern for humans owing to possible developmental toxic effects, generally on the basis of either: results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in category 2; or other relevant information.</p> <p>The placing of a compound in category 1 for effects on fertility and/or developmental toxicity is done on the basis of epidemiological data. Placing in categories 2 or 3 is done primarily on the basis of animal data. Data from in vitro studies, or studies on avian eggs, are regarded as ‘supportive evidence’ and would only exceptionally lead to classification in the absence of in vivo data.</p> <p>Annex V to the Directive specifies a limit test in the case of substances of low toxicity. If a dose level of at least 1000 mg/kg orally produces no evidence of effects toxic to reproduction, studies at other dose levels may not be considered necessary. If data are available from studies carried out with doses higher than the above limit dose, this data must be evaluated together with other relevant data. Under normal circumstances it is considered that effects seen only at doses in excess of the limit dose would not necessarily lead to classification as ‘Toxic to reproduction’.</p>	
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Use	Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation	Draft REACH regulation
Use and exposure category	An exposure scenario covering a wide range of processes or uses.	Draft REACH regulation
Vapour	The gaseous form of a substance or mixture released from its liquid or solid state.	GHS 2005
Very toxic	<p>Substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.</p> <p>Criteria for acute oral toxicity:</p> <ul style="list-style-type: none"> (a) LD_{50} (rat) \leq 25 mg/kg (b) Less than 100% survival at 5 mg/kg (rat) by the fixed dose procedure (c) High mortality at doses \leq 25 mg/kg (rat) by the acute toxic class method <p>Criteria for acute dermal toxicity:</p> <ul style="list-style-type: none"> (a) LD_{50} (rat, rabbit) \leq 50 mg/kg <p>Criteria for acute inhalation toxicity:</p> <ul style="list-style-type: none"> (a) LC_{50} (rat) \leq 0.25 mg/litre/4 h (aerosols or particulates) (b) LC_{50} (rat) \leq 0.50 mg/litre/4 h (gases and vapours) <p>Or strong evidence that irreversible damage other than [specific CMR effects] is likely to be caused by a single exposure by an appropriate route, generally in the above-mentioned dose range.</p> <p>[See also toxic, and harmful]</p>	67/548/EEC