

Guidance for harmonisation of first aid
instructions in the authorisation of biocidal
products

Introduction

The present guidance document for first aid instructions has been compiled by the Swedish CA in cooperation with the Swedish Poisons Information Centre and was accepted during the CG-43 meeting.

According to Art 22 (Content of authorisation) of the BPR (528/2012), the summary of the biocidal products characteristics (SPC) shall include, among other, information on “particulars of likely direct or indirect adverse effects and first aid instructions” (Art 22.2n). Furthermore, according to Art 69 (Classification, packaging and labelling of biocidal products), the label must clearly and indelibly show, among other, the following information “particulars of likely direct or indirect adverse side effects and any directions for first aid” (Art 69.2.h). In addition, point 11.3 of Annex III states that specific treatment in case of an accident such as first aid measures, is one of the requirements to support the authorisation of a biocidal product.

The aim of this guidance is to have relevant, safe and harmonised first aid instructions included in the SPC, which would favour the best outcome for the person involved in an accident or poisoning. This harmonised approach will also contribute to a more effective process during mutual recognition and union authorisations.

Description of approach

In order to give adequate treatment and to simplify for the user of this guidance, the first aid instructions are based on hazard classifications and specific hazard statements (H-statements) under the CLP Regulation. Furthermore, with the purpose to uniform with already used statements, the response precautionary statements (P-statements) from the CLP Regulation, are used as a base for the first aid instructions. However, based on expert judgement within clinical toxicology, the P-statements have in relevant cases been modified to better suit the treatment regimens, aiming for the best adequate treatment of the affected patient of an accident/poisoning.

One must be aware that first aid instructions in the SPCs are not the same as the set of precautionary statements on the CLP hazard labels. CLP labels must bear the relevant precautionary statements giving advice on *measures to prevent or minimise adverse effects* to human health *arising from the hazard classification* of a substance or mixture. Whereas the purpose of the first aid instructions is that they should instruct a person in a stressful situation, on *how to act if an accident or poisoning has occurred*. Moreover, first aid instructions should include all relevant exposure routes even if there is no risk identified with the exposure.

Every accident/poisoning is individual and often needs expert judgement by a poison centre or a clinical toxicologist. Therefore, the proposed first aid instructions are kept simple and general and are frequently referring the exposed person to a poison information centre or a doctor.

The instructions for the health care personnel (regarding antidotes and medical treatment) are very basic, because as stated above, expert knowledge is needed to give relevant advice on specific treatment. In addition, there are different treatment regimens in different countries and even within one country, the capacity of the hospitals and the knowledge on how to treat chemical accidents or poisonings differs at different hospitals. Also, the tradition of who to contact in a poisoning, a poison information centre or a doctor, differs between countries. In some countries the general public can call a poison information centre, whereas in other countries only doctors are allowed to contact the poison centre. The following text is added in the guidance of instructions: **Call a POISON CENTRE or a doctor**. A national adaptation of this instruction can be made in the SPCs.

The proposed first aid instructions are the same regardless if the exposed person is professional or non-professional users, as the classification do not differ if the biocidal product is the same. The phrases have also been constructed in a general manner to suit all kind of product types and formulations.

First aid instructions

H-statements cover either local or systemic effects. In a case where both local and systemic symptoms could occur by the same exposure route, the first aid instructions from local and systemic effects must be prioritised and combined. Certain hazard statements (fatal, toxic, corrosive) provide more urgent risks with more rapid actions needed. In these cases, a substance classified as fatal, acutely toxic or corrosive, will take precedence over other classifications (harmful, irritation) and thereby the first aid instructions coupled to the most severe classification will be used. However, if there are biocidal products where more than one first aid instruction can be added for the same route of exposure, but none of the coupled classifications will take precedence, the first aid instructions should be combined.

Local effects

Inhalation – local effects

Hazard statements	Precautionary statements	First aid instruction	Justification/Guidance
<p>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled/H335 May cause respiratory irritation /H314 Causes severe skin burns and eye damage /EUH071 Corrosive to the respiratory tract</p>	<p>P304 P340 P342 P311/P312/P310</p>	<p>IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.</p> <p>If symptoms: Call 112/ambulance for medical assistance.</p> <p>If no symptoms: Call a POISON CENTRE or a doctor.</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justification below:</p> <p>After inhalation of substances that could cause irritation/breathing difficulties, it is important to keep the person at rest because extensive body labour could make the symptoms more severe.</p> <p>Many persons promptly experience serious breathing difficulties and need medical assistance on their way to the hospital.</p> <p>It is important to call a poison centre or a doctor even if no initial symptoms occur because there may be delayed pronounced symptoms, sometimes without initial indications.</p>
<p>Inhalation of chemicals without classification</p>		<p>IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.</p>	<p>For clarification, all exposure routes should have an instruction. The need for measures for a specific product must be decided case-by-case. If a formulation is non-inhalable due to formulation type (e.g. a non-volatile, solid product), the following should be stated: not applicable.</p>

Ingestion – local effects

If a product has both eye- and skin classification and first aid instructions for ingestion are to be added. Prioritise the phrases triggered by H314 or H318 before the ones triggered by H315 or H319.

Hazard statements	Precautionary statements	First aid instruction	Justification/Guidance
H314 Causes severe skin burns and eye damage /H318 Causes serious eye damage	P301 P330 P331 (H318: P-statements do not cover ingestion)	IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.	The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below: It is crucial to give something to drink ¹ directly after ingestion of a corrosive chemical because the liquid will shorten the exposure time of the chemical in the esophagus and it might decrease symptoms. However, the person has to be able to swallow. The type of drink is not specified as it is of lower importance than having something to drink as quick as possible. Vomiting after ingesting a corrosive chemical is contraindicated, as the regurgitating chemical will corrode on the way up. After having ingested a corrosive chemical it is very important to urgently go to a hospital. Not only because of the risk of corrosive injuries but also because the risk of potential prompt swelling of the upper airway causing severe breathing difficulties ^{2 3} .
H315 Causes skin irritation	P-statements do not cover ingestion	IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is	A chemical that irritates skin, most likely irritates the gastrointestinal tract as well. To decrease symptoms, rinsing of the mouth, giving

¹ Weigert, A. Black, A. Caustic ingestion in children. Continuing education in anaesthesia, Critical care & pain, vol 5 (1), 2005.

² Bird, J.H. Kumar, S. Paul, C. Ramsden, J.D. Controversies in the management of caustic ingestion injury: an evidence-based review. Clin Otolaryngology, vol 42 (3), 701-708, 2016.

³ Rollin, M. Jaulim, A. Vaz, F. Sandhu, G. Wood, S. Birchall, M. Dawas, K. Caustic ingestion injury of the upper aerodigestive tract in adults. Ann R Coll Surg Engl, vol 97, 304-307, 2015.

/H319 Causes serious eye irritation		able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.	something to drink and contacting a poison centre or a doctor would be necessary. The type of drink is not specified as it is of lower importance than having something to drink.
Ingestion of chemicals without classification		IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.	For clarification, all exposure routes should have an instruction. If chemicals without classification is ingested there is no need seeking medical advice unless symptoms occur. In cases where ingestion is unlikely to happen (e.g. exposure to gases) “not applicable” could be added instead.

Skin contact – local effects

Hazard statements	Precautionary statements	First aid instruction	Justification/Guidance
H314 Causes severe skin burns and eye damage /H318 Causes serious eye damage	P303 P361 P353 P363 (H318: P-statements do not cover skin contact)	IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.	The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below: It is highly important to minimise the exposure time and therefore the patient should start to wash immediately even before taking of the contaminated clothing. After washing has started the next step will be removing of the contaminated clothing, as corrosion could be severe under occlusion (under clothes). In this case it is important to wash the skin for a long time. For alkaline chemicals which are very hard to rinse off, a rinsing time of about 15 minutes might be needed ⁴ and should be specified in the instructions. The applicant can add soap for skin decontamination in relevant cases if the product is less water soluble.
H315 Causes skin irritation /EUH066 Repeated exposure may cause skin dryness or cracking	P302 P313 P352 P362 P321 P364 P332	IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.	The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below: The applicant can add soap for skin decontamination in relevant cases if the product is less water soluble. For biocides that are to be applied on skin, like repellents or hand disinfection products, only the part of the skin that were not supposed to be exposed should be washed. If irritation occurs the skin should be washed and medical advice should be sought.
H317 May cause an allergic skin reaction	P302 P321	IF ON SKIN: Take off all contaminated clothing and	The applicant can add soap for skin decontamination in relevant cases if the product is less water soluble.

⁴ Brent, J. Water-based solutions are the best decontaminating fluids for dermal corrosive exposures: a mini review. Clin. Tox, vol 51 (8), 731-736, 2013.

/EUH208 Contains (name of sensitising substance). May produce an allergic reaction	P352 P333 P313	P362 P364	wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.	
Skin contact with chemicals without classification		IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.	For clarification, all exposure routes should have an instruction. Even if the chemical does not imply a risk the skin should be rinsed, but no more measures are needed unless symptoms occur. For biocides that are to be applied on skin, like repellents or hand disinfection products, only the part of the skin that were not supposed to be exposed should be washed. If irritation occurs the skin should be washed and medical advice should be sought.	

Eye exposure – local effects

Hazard statements	Precautionary statements	First aid instruction	Justification/Guidance
H314 Causes severe skin burns and eye damage /H318 Causes serious eye damage	P305 P351 P338 P310	<p>IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.</p> <p><u>Information to Healthcare personnel/doctor:</u></p> <p>The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>The prognosis of the eye injury depends on the promptness and effectiveness of the irrigation. Immediate and continuous irrigation for at least 15 minutes⁵ can reduce the severity in alkali burns of the eye and shorten the healing time. Washing with tepid water is usually the most convenient for the eyes, but as minimising the exposure time is of outmost importance it is better to start washing the eyes regardless of the temperature of the water (if not too hot).</p> <p>When alkaline chemicals like sodium- and potassium hydroxide and organic acids like formic or acetic acid get in the eyes they penetrate the tissue and the damage could be extensive. Because of the penetrating properties, the rinsing time should be prolonged, and the eyes should be rinsed repeatedly on the way to the doctor/hospital⁶.</p> <p>According to the Swedish Poisons Information Centre, corrosive damage of the eyes can be seen from pH 11⁷. The justification they give is that the tissue of the eye is more sensitive than the skin and therefore a lower pH than 11,5 could damage the eye.</p>
H319 Causes serious eye irritation /H315 Causes skin irritation	P305 P337 P351 P313	<p>IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p>

⁵ The American National standards institute (ANSI) standard (Z358.1-1990)

⁶ Kuckelkorn, R. Schrage, N. Keller, G, Redbrake, C. Emergency treatment of chemical and thermal eye burns. Acta Ophthalmol. Scand. Vol 80, 4-10, 2002.

⁷ The Swedish Poisons Information Centre, Ögonskador (Eye damages). Internal document, 1998.

	P338	rinsing for 5 minutes. Call a POISON CENTRE or a doctor.	<p>According to the Swedish Poison Information Centre, 5 minutes rinsing time is enough if eyes have been exposed to irritating substances.</p> <p>A prolonged rinsing time will increase the discomfort of the eye and should be avoided if not deemed necessary. Chemicals that causes eye irritation would not penetrate the tissue of the eye, therefore the rinsing time could be shorter than for corrosives.</p>
Eye exposure to chemicals without classification		IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.	<p>For clarification, all exposure routes should have an instruction. If the chemical causes symptoms upon eye contact the eyes should be rinsed in order to remove the chemical.</p> <p>Local effects usually develop shortly after exposure. Thereby, there is no risk if no rinsing is performed when a patient is asymptomatic.</p>

Systemic effects

Inhalation – systemic effects

Hazard statements	Precautionary statements	First aid instruction	Justification/Guidance
H330 Fatal if inhaled/H331 Toxic if inhaled	P304 P340 P310/P311 P320/P321	<p>IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.</p> <p><u>Information to Healthcare personnel/doctor:</u></p> <p>Immediately initiate life support measures, thereafter call a POISON CENTRE.</p> <p>Antidote: (if any available)</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>For a potentially fatal poisoned patient the time from exposure to treatment is crucial. Therefore, the patient should be referred to a hospital as soon as possible instead of calling a poison centre or a doctor.</p> <p>Few poisonings can be treated by administration of antidote.</p> <p>Insert information on antidote when there is an available.</p>
H332 Harmful if inhaled	P304 + P340 P312	<p>IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.</p> <p>If symptoms: Call 112/ambulance for medical assistance.</p> <p>If no symptoms: Call a POISON CENTRE or a doctor.</p> <p><u>Information to Healthcare personnel/doctor:</u></p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>It is important not to wait until symptoms occur before calling a poison centre or a doctor because early treatment is often beneficial for the patient.</p> <p>Few poisonings can be treated by administration of antidote.</p> <p>Insert information on antidote when there is an available.</p>

		<p>Initiate life support measures if needed, thereafter call a POISON CENTRE.</p> <p>Antidote: (if any available)</p>	
H336 May cause drowsiness or dizziness	P304 + P340 P312	IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>It is important not to wait until symptoms occur before calling a poison centre or a doctor because early treatment is often beneficial for the patient.</p>
Inhalation of chemicals without classification		IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.	<p>For clarification, all exposure routes should have an instruction. The need for measures for a specific product must be decided case-by-case. If a formulation is non-inhalable, due to formulation type, the following should be stated: Not applicable.</p>

Ingestion – systemic effects

Hazard statements	Precautionary statements	First aid instruction	Justification/Guidance
<p>H300 Fatal if swallowed/ H301 Toxic if swallowed</p>	<p>P301 P310 P321 P330</p>	<p>IF SWALLOWED: If conscious: Immediately rinse mouth. Keep at rest in a position comfortable for breathing. Call 112 /ambulance for medical assistance.</p> <p><u>Information to Healthcare personnel/doctor:</u></p> <p>Immediately initiate life support measures, thereafter call a POISON CENTRE.</p> <p>Antidote: (if any available)</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>For a potentially fatal poisoned patient the time from exposure to treatment is crucial. Therefore, the patient should be referred to a hospital as soon as possible instead of calling a poison centre or a doctor.</p> <p>The responding doctor/healthcare personnel should stabilise the patient and then as soon as possible call a poison centre/clinical toxicologist to discuss elimination of the swallowed substance.</p> <p>Few poisonings can be treated by administration of antidote.</p> <p>Insert information on antidote when available.</p>
<p>H302 Harmful if swallowed /H336 May cause drowsiness or dizziness* / Ingestion of rodenticides**</p>	<p>P301 P312 P330</p>	<p>IF SWALLOWED: Rinse mouth.</p> <p>If symptoms: Call 112/ambulance for medical assistance.</p> <p>If no symptoms: Call a POISON CENTRE or a doctor.</p> <p><u>Information to Healthcare personnel/doctor:</u> Initiate life support measures if needed,</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>When something harmful has been ingested and no symptoms have occurred, it is important not to wait until systemic symptoms develop before calling a poison centre/doctor, because early treatment is often beneficial for the patient.</p> <p>Few poisonings can be treated by administration of antidote.</p> <p>Insert information on antidote when available.</p> <p>* When the biocidal product contains an alcohol (e.g. ethanol, isopropanol) ingestion might lead to nausea and vomiting due to local</p>

		<p>thereafter call a POISON CENTRE.</p> <p>Antidote: (if any available)</p>	<p>irritation and systemic effects like drunkenness, drowsiness, sometimes unconsciousness and low blood sugar (especially in children). Therefore H336 can trigger this first aid instruction.</p> <p>**For rodenticides regardless of the concentration and classification this phrases should be used.</p>
H304 May be fatal if swallowed and enters airways	P301 P310 P331	<p>IF SWALLOWED: Do NOT induce vomiting.</p> <p>If symptoms: Immediately call 112/ambulance for medical assistance.</p> <p>If no symptoms: Call a POISON CENTRE or a doctor.</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>Inducing vomiting is contraindicated since vomiting could cause aspiration of the chemical and thereby symptoms.</p> <p>The symptoms that occur is extensive coughing, breathing difficulties and vomiting and in some cases lethargy.</p> <p>Be aware that all petroleum based products could cause aspiration and thereby chemical pneumonia, not only the products classified as H304.</p>
Ingestion of chemicals without classification		<p>IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.</p>	<p>For clarification, all exposure routes should have an instruction. If chemicals without classification is ingested there is no need seeking medical advice unless symptoms occur.</p> <p>In cases were ingestion is unlikely to happen (e.g. exposure to gases) “not applicable” could be added instead.</p>

Skin contact – systemic effects

Hazard statement	Precautionary statements	First aid instructions	Justification/Guidance
<p>H310 Fatal in contact with skin/H311 Toxic in contact with skin</p>	<p>P302 P352 P310/P312 P321 P361 P364</p>	<p>IF ON SKIN: Immediately wash skin with plenty of <u>water</u>. Take off all contaminated clothing and wash it before reuse. After washing the skin: Call 112/ambulance for medical assistance.</p> <p><u>Information to Healthcare personnel/doctor:</u></p> <p>Initiate life support measures, thereafter call a POISON CENTRE.</p> <p>Antidote: (if any available)</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>It is highly important to minimise the exposure time and therefore the patient should start to wash immediately, even before taking of the clothing. After washing has started the next step will be removing of the contaminated clothing, as absorption could increase under occlusion (under clothes).</p> <p>The applicant can add soap for skin decontamination in relevant cases if the product is less water soluble.</p> <p>Because of the highly toxic chemical, the patient must go to the hospital even if asymptomatic.</p> <p>It is important not to wait until systemic symptoms occur, because early treatment, before symptoms occur, is often beneficial for the patient and could in this case be crucial.</p> <p>Few poisonings can be treated by administration of antidote.</p> <p>Insert information on antidote when available.</p>
<p>H312 Harmful in contact with skin</p>	<p>P302 P352 P312 P321 P362 P364</p>	<p>IF ON SKIN: Wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse.</p> <p>If symptoms: Call 112 /ambulance for medical assistance.</p>	<p>The first aid instructions differ compared to the precautionary statements due to the safety of the exposed person, see the justifications below:</p> <p>It is highly important to minimise the exposure time and therefore the patient should start to wash, even before taking of the clothing.</p> <p>The applicant can add soap for skin decontamination in relevant cases if the product is less water soluble.</p>

		<p>If no symptoms: Call a POISON CENTRE or a doctor.</p> <p><u>Information to Healthcare personnel/doctor:</u></p> <p>Initiate life support measures if needed, thereafter call a POISON CENTRE.</p> <p>Antidote: (if any available)</p>	<p>It is important not to wait until symptoms occur before calling a poison centre or a doctor because early treatment, before symptoms occur, is often beneficial for the patient.</p> <p>Few poisonings can be treated by administration of antidote.</p> <p>Insert information on antidote when available.</p>
Skin contact with chemicals without classification		<p>IF ON SKIN: If symptoms occur call a POISON CENTRE or a doctor.</p>	<p>For clarification, all exposure routes should have an instruction. Even if the chemical does not imply a risk the skin should be rinsed, but no more measures are needed unless symptoms occur.</p>

Eye exposure – systemic effects

Hazard statement	Precautionary statements	First aid instruction	Justification/Guidance
EUH070 Toxic by eye contact		IF IN EYES: Immediately rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call 112/ambulance for medical assistance.	EUH070 is applied if there is evidence for systemic toxicity after eye contact. Due to the risk of systemic toxicity the patient needs to go to hospital urgently.

Specific target organ toxicity and cryogenic burns

Hazard statement	Precautionary statements	First aid instructions	Justification/Guidance
Single exposure: H370 Causes damage to organs/ H371 May cause damage to organs	P308 P311 P321	IF EXPOSED: Call a POISON CENTRE or a doctor.	A poison centre or a doctor should be contacted in order to give advice on treatment. This is important even if the exposed person is asymptomatic.
Repeated exposure: H372 Causes damage to organs	P314	IF EXPOSED: Call a POISON CENTRE or a doctor.	A poison centre or a doctor should be contacted in order to give advice on treatment. This is important even if the exposed person is asymptomatic.
H281 Contains refrigerated gas; may cause cryogenic burns or injury	P336 P315	IF EXPOSED: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.	Normally physical hazards are not included in the first aid, but when it comes to frostbites from refrigerated gas it becomes a medical hazard and is therefore included in this guidance.

Mutagenicity, carcinogenicity and reproductive toxicity

Hazard statement	Precautionary statements	First aid instructions	Justification/Guidance
H340 May cause genetic defects / H341 Suspected of causing genetic defects	P308 P313	IF EXPOSED OR CONCERNED: Get medical advice/attention.	A doctor should be contacted in order to give advice on treatment. This is important even if the exposed person is asymptomatic.
H350 May cause cancer / H351 Suspected of causing cancer	P308 P313	IF EXPOSED OR CONCERNED: Get medical advice/attention.	A doctor should be contacted in order to give advice on treatment. This is important even if the exposed person is asymptomatic.
H360 May damage fertility or the unborn child / H361 Suspected of damaging fertility or the unborn child / H362 May cause harm to breast-fed children	P308 P313	IF EXPOSED OR CONCERNED: Get medical advice/attention.	A doctor should be contacted in order to give advice on treatment. This is important even if the exposed person is asymptomatic.