CLAIMS

1. A process for purifying a recombinant polypeptide from a solution comprising one or more impurities, wherein the process is an affinity chromatography process which comprises the addition of saccharin, wherein the saccharin concentration is 0.01 to 4 M~~, and wherein the saccharin is not used to displace the recombinant polypeptide from a chromatography support~~.

~~2. The process according to claim 1, wherein the process comprises affinity chromatography; ion exchange chromatography; anion exchange chromatography; cation exchange chromatography; gel-permeation or gel filtration chromatography; dye-ligand chromatography;hydrophobic interaction chromatography (HIC); mixed mode chromatography (MMC); and/or ceramic hydroxyapatite chromatography.~~

~~3~~2. The process according to claim 1~~ or 2~~, wherein the process comprises: (a) a loading step; and/or (b) a washing step.

~~4~~3. The process according to ~~any of~~ claim~~s~~ 1 ~~to~~ or 2~~3~~, wherein the process comprises one or more chromatography steps (a)~~,~~ and/or (b):

(a) loading a solution comprising the recombinant polypeptide and one or more impurities onto a chromatography support;

(b) washing the chromatography support with a wash buffer;~~.~~

wherein at least one of steps (a) and/or (b) comprises the addition of saccharin.

~~5~~4. The process according to any of claims 1 to ~~4~~ 3 wherein the chromatography is Protein A affinity chromatography.

~~6~~5. The process according to any preceding claim wherein the solution comprising the recombinant polypeptide and one or more impurities, is a cell culture feedstream, or a clarified cell culture ~~fluid~~supernatant.

~~7~~6. The process according to any preceding claim wherein the recombinant polypeptide is an antigen binding protein.

~~8~~7. The process according to claim ~~7~~ 6 wherein the antigen binding protein is an antibody.

~~9~~8. The process according to any preceding claim wherein the one or more impurities are derived from a mammalian cell.

~~10~~9. The process according to claim ~~9~~ 8 wherein the mammalian cell is selected from: CHO; NS0; Sp2/0; COS; K562; BHK; PER.C6; and/or HEK cells.

~~11~~10. The process according to any preceding claim wherein the one or more impurities in the process are one or more of: host cell proteins (HCPs), nucleic acids, endotoxins, and/or cell culture media associated impurities.

11. The process according to claim 10, wherein the nucleic acid is host cell DNA.

12. The process according to claim 10, wherein the host cell protein is phospholipase B-like 2 protein (PLBL2).

~~12~~13. The process according to any preceding claim wherein the saccharin concentration is 0.01-3.0 M or 0.05-1.0 M; or 0.3-1.5M.

~~13~~14. The process according to any preceding claim wherein the solution, load buffer/loading step, wash buffer/washing step, and/or elution buffer/eluting step further comprises arginine; and/or caprylate; and/or lysine; and/or sodium acetate.

~~14~~15. The process according to any preceding claim wherein saccharin is added to the solution, load buffer, and/or wash buffer.

16. The process according to claim 15, wherein the buffer is at a pH of 5 to 9.

~~15~~17. The process according to any preceding claim wherein saccharin is in the form of 2-sulfobenzoic acid ammonium salt; saccharin sodium salt dihydrate; or saccharin sodium salt hydrate.

~~16~~18. The process according to any preceding claim wherein the purified recombinant polypeptide is further purified.

~~17~~19. The process according to any preceding claim wherein the purified recombinant polypeptide is formulated to a final therapeutic formulation.

~~18. A wash or load buffer for purifying using chromatography a recombinant polypeptide from a solution comprising one or more impurities, wherein the wash or load buffer comprises saccharin, and wherein the saccharin concentration is 0.01 to 4 M.~~

~~19. A cell culture feedstream comprising a recombinant polypeptide and one or more impurities, wherein the feedstream is a solution comprising saccharin, and wherein the saccharin concentration is 0.01 to 4 M.~~

20. Use of saccharin in a process for purifying a recombinant polypeptide from a solution comprising one or more impurities, wherein the process is an affinity chromatography process, wherein the saccharin concentration used in the process is 0.01 to 4 M~~, and wherein the saccharin is not used to displace the recombinant polypeptide from a chromatography support~~.